MESSING WITH SUCCESS: HOW CMS' ATTACK ON THE PART D PROGRAM WILL INCREASE COSTS AND REDUCE CHOICES FOR SENIORS

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

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C O N T E N T S

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[1] The memorandum and the report are available at http://docs.house.gov/meetings/IF/IF14/20140226/101788/HHRG-113-IF14-20140226-SD006.pdf.

MESSING WITH SUCCESS: HOW CMS' ATTACK ON THE PART D PROGRAM WILL INCREASE COSTS AND REDUCE CHOICES FOR SENIORS

WEDNESDAY, FEBRUARY 26, 2014

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON ENERGY AND COMMERCE
Washington, DC.

The subcommittee met, pursuant to call, at 10:01 a.m., in room 2123 of the Rayburn House Office Building, Hon. Joseph R. Pitts (chairman of the subcommittee) presiding.

Members present: Representatives Pitts, Burgess, Shimkus, Murphy, Blackburn, Gingrey, Lance, Cassidy, Guthrie, Griffith, Bilirakis, Ellmers, Barton, Pallone, Capps, Schakowsky, Green, Barrow, Christensen, Castor, Sarbanes, and Waxman (ex officio).

Staff present: Clay Alspach, Chief Counsel, Health; Sean Bonyun, Communications Director; Matt Bravo, Professional Staff Member; Karen Christian, Chief Counsel, Oversight and Investigations; Noelle Clemente, Press Secretary; Paul Edattel, Professional Staff Member, Health; Brad Grantz, Policy Coordinator, Oversight and Investigations; Sydne Harwick, Legislative Clerk; Sean Hayes, Counsel, Oversight and Investigations; Robert Horne, Professional Staff Member, Health; Peter Kielty, Deputy General Counsel; Chris Pope, Fellow, Health; Chris Sarley, Policy Coordinator, Environment and the Economy; Heidi Stirrup, Policy Coordinator, Health; Josh Trent, Professional Staff Member, Health; Ziky Ababiya, Democratic Staff Assistant; Phil Barnett, Democratic Staff Director; Eddie Garcia, Democratic Professional Staff Member; Kaycee Glavich, Democratic GAO Detailee; Amy Hall, Democratic Senior Professional Staff Member; Karen Lightfoot, Democratic Communications Director and Senior Policy Advisor; and Karen Nelson, Democratic Deputy Staff Director, Health.

Mr. PITTS. The subcommittee will come to order. The Chair recognizes himself for an opening statement.

OPENING STATEMENT OF HON. JOSEPH R. PITTS, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

The Medicare Part D Prescription Drug Benefit is a government success story. Last year, nearly 39 million beneficiaries were enrolled in a Part D prescription drug plan. Competition and choice have kept premiums stable. In fact, in 2006, the first year the pro-

gram was in effect, the base beneficiary premium was $32.20 a month. In 2014, the base beneficiary premium is $32.42; a 22-cent increase over 9 years, and still roughly half of what was originally predicted. More than 90 percent of seniors are satisfied with their Part D drug coverage because of this. African-American and Hispanic seniors report even higher levels of satisfaction, at 95 percent and 94 percent, respectively.

The program has worked so well because it forces prescription drug plans and providers to compete for Medicare beneficiaries, putting seniors, not Washington, in the driver's seat. Part D should be the model for future reforms to the Medicare Program. Instead, in its January 6, 2014, proposed rule, the Centers for Medicare & Medicaid Services, CMS, proposes to dismantle the very features of the program that have made it so popular and successful. CMS has taken it upon itself to interpret the noninterference clause in the statute to mean that it can interfere with negotiations between plans and pharmacies. Congress expressly created the clause to prevent CMS from doing what it intends to do in this rule, yet CMS is choosing to ignore the law.

The proposed rule seeks to essentially eliminate preferred pharmacy networks. A 2013 Milliman Study shows that preferred pharmacy networks will save taxpayers $870 million this year, and anywhere from $7.9 billion to $9.3 billion over the next 10 years. CMS itself says that 96 percent of the Part D claims it reviewed showed seniors saved money at preferred pharmacies, and nearly 25,500 seniors in my congressional district have chosen Part D plans with a preferred pharmacy network, yet CMS would take that away from them.

Today, the average senior has 35 different plans to choose from this year. This rule would reduce that choice to 2 plans. Fifty percent of the plans offered today will be gone, and the healthcare that seniors like may go with it. Limiting seniors' choices like this will inevitably lead to higher cost. By some estimates, the restrictions on the number of plans that could be offered could cause premiums to rise by 10 to 20 percent. Cost to the Federal Government may increase by $1.2 to $1.6 billion, according to a study by Milliman.

How is this beneficial? I am at a loss to understand why CMS has proposed these changes, and what problems with the Part D Drug Benefit it is attempting to solve. I don't see how any of these proposals provide tangible benefits to seniors, but I do see more bureaucracy, less choice and competition, and higher cost to both beneficiaries and the Federal Government in the future if the proposed rule is enacted.

I urge Secretary Sebelius and Administrator Tavenner to rescind this rule. And I welcome our witnesses here today. I look forward to their testimony.

[The prepared statement of Mr. Pitts follows:]

PREPARED STATEMENT OF HON. JOSEPH R. PITTS

The Medicare Part D prescription drug benefit is a government success story.

Last year, nearly 39 million beneficiaries were enrolled in a Part D prescription drug plan (PDP).

Competition and choice have kept premiums stable. In fact, in 2006, the first year the program was in effect, the base beneficiary premium was $32.20 a month. In 2014, the base beneficiary premium is $32.42—a 22-cent increase over 9 years—and still roughly half of what was originally predicted.

More than 90 percent of seniors are satisfied with their Part D drug coverage because of this. African-American and Hispanic seniors report even higher levels of satisfaction, at 95 percent and 94 percent, respectively.

The program has worked so well because it forces prescription drug plans and providers to compete for Medicare beneficiaries—putting seniors, not Washington, in the driver's seat.

Part D should be the model for future reforms to the Medicare program.

Instead, in its January 6, 2014, proposed rule, the Centers for Medicare & Medicaid Services (CMS) proposes to dismantle the very features of the program that have made it so popular and successful.

CMS has taken it upon itself to interpret the "noninterference" clause in the statute to mean that it can interfere with negotiations between plans and pharmacies. Congress expressly created the clause to prevent CMS from doing what it intends to do in this rule. Yet CMS is choosing to ignore the law.

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Today, the average senior has 35 different plans to choose from this year. This rule would reduce that choice to two plans. Fifty percent of the plans offered today will be gone, and the health care that seniors like may go with it.

Limiting seniors' choices like this will inevitably lead to higher costs. By some estimates, the restriction on the number of plans that can be offered could cause premiums to rise by 10–20 percent. Costs to the Federal Government may increase by $1.2 to 1.6 billion, according to a study by Milliman.

How is this beneficial?

I am at a loss to understand why CMS has proposed these changes and what problems with the Part D drug benefit it is attempting to solve.

I don't see how any of these proposals provide tangible benefits to seniors, but I do see more bureaucracy, less choice and competition, and higher costs to both beneficiaries and the Federal Government in the future if the proposed rule is enacted.

I urge Secretary Sebelius and Administrator Tavenner to rescind this rule.

I welcome our witnesses here today, and I look forward to their testimony.

Mr. PITTS. Thank you, and I yield the remainder of my time to the gentlelady from Tennessee, Mrs. Blackburn.

OPENING STATEMENT OF HON. MARSHA BLACKBURN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE

Mrs. BLACKBURN. Thank you, Mr. Chairman. I thank you for the hearing today, and I have to agree with you, Medicare Part D is very popular with seniors, and the majority of beneficiaries not only participate in Part D, they express satisfaction with the program, and it is definitely working the way it was intended.

I join you in being very concerned about the rule and the proposed rule. This is something that would not serve groups well, certainly not my seniors in Tennessee. There are over 250 groups which include patients and physicians that oppose the rule, and I would like to submit a letter from an organization, Centerstone. I submit that for the record. They provide mental health care in Tennessee.

Mr. PITTS. Without objection, so ordered.

[The information follows:]

CENTERSTONE

February 18, 2014

Marilyn Tavenner, Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Proposed rule seeking to change protected drug classes in Medicare Part C (Medicare Advantage) and Medicare Part D.

Dear Administrator Tavenner,

In January, the Center for Medicare and Medicaid Services (CMS) proposed new regulations for Medicare Part D that, if implemented, we believe, will reduce benefits to beneficiaries as well as interfere with the time honored patient – physician relationship. We wish to express concerns regarding the proposed rule to revise the prescription drug benefit in Medicare Part C (Medicare Advantage) and Medicare Part D. We are specifically concerned regarding Section III.A.14 of the proposed rule which will significantly reverse the agency's policy towards protected classes of prescription drugs.

As psychiatrists and leaders of community mental health providers with over fifty years' experience caring for persons with psychosis-related disorders in the community, we believe that antipsychotic medications fully meet the two statutory specifications defined in the past protected classes. These were specifications regarding 1) restricted access to the drugs could result in major or life-threatening clinical consequences, and 2) there is a significant need for access to multiple drugs within a category due to unique chemical actions and pharmacological effects of the drug. From reading the report of your Protected Classes Review Panel, we see that while your panel agrees with us regarding #1, it disagrees regarding #2.

In page four of the Review Panel report, they write:

> "The panel concluded, however, that antipsychotics did not meet the non-interchangeability criteria. The APA developed practice guidelines for the treatment of schizophrenia in 2004 and 2009 that discuss initial selection of these agents in broad terms such as "first" and "second" generation antipsychotics. These guidelines do not recommend specific products over one another, and the 2009 updated guidelines note that the distinction between first and second generation antipsychotics appears to have limited clinical utility. These drugs are normally not used in combination with each other for an additive effect, but they are used in combination with other psychiatric medications to treat symptoms such as depression or anxiety, or in combination with non-pharmacological psychosocial treatments. In addition, there is a high discontinuation rate with all of these medications, which would lead one to conclude that there are multiple options for initiation of pharmacological

> therapy in these patients. The Part D program allows beneficiaries and clinicians options to obtain formulary exceptions if one particular agent seems to work better than others for a given patient. As a therapeutic class, antipsychotic agents are noted to cause an increased risk of death in patients who have dementia-related psychosis leading to a black box warning in the FDA-approved labeling for these agents. Unfortunately, CMS' analyses suggest that these agents continue to be prescribed within long term care facilities at an alarming rate. The panel did not determine that additional protections were necessary for antipsychotics based on current protections afforded by our treatment guideline check as well as the nature of the recommendations within the treatment guidelines."[1]

In reading your panel's justification for antipsychotics not meeting the non-interchangeability criteria, we believe that their reasoning is based on several assumptions that, from our experience and understanding of current research, seems to be inaccurate justifications against the need for access to multiple drugs within this category.

First of all, we believe that the argument regarding American Psychiatric Association (APA) treatment guidelines is inaccurately rendered and taken out of context. From a chemical perspective, there are significant differences between and within first, second, and third generation antipsychotic medications.[2, 3, 4] Antipsychotics have "the most complex pharmacological mechanisms of any drug class within the field of clinical psychopharmacology" (Stahl, 2103, p. 130).[5] Each drug is unique because they each have very different profiles with regards to their effects on receptors. These medications are not equivalent in their side effects profiles or efficacy.[6, 7] Each medication is different regarding which receptors (dopamine, serotonin, histamine, etc) are targeted and blocked, and there are distinct differences in pharmacodynamic profiles between the various medications. Certain medications cause more weight gain or hyperlipidemia in some patients than others, and some cause life-long extra-pyramidal symptoms (i.e. shaking of hands, etc). In addition, this variation of effect on patients is undoubtedly influenced significantly by factors not yet completely understood, such as each individual person's genetic makeup.

For example, clozapine, a generic "second generation" atypical antipsychotic medication, is the only antipsychotic medication that has FDA approval to reduce suicidality with schizophrenia.[8, 9] This medication is proven to extend life[10] and reduce hospitalizations for persons with schizophrenia with a history of hospitalizations, and it has been lamented in *Health Affairs* as greatly underutilized as a medication option for persons with schizophrenia.[11] However, it is also an antipsychotic medication that has been shown to cause agranulocytosis, a dangerous and possibly lethal side effect if not properly monitored by a psychiatrist. For individuals that do not develop agranulocytosis, clozapine can be a life-saving (and cost-effective, since it is a generic) treatment choice. For those individuals who do develop agranulocytosis, it should never be prescribed again.

Your review panel noted that using two or more antipsychotic medications simultaneously is not typical best practice. While we agree generally with this comment, each of us has had patients who did require more than one antipsychotic medication at a time. Furthermore, it is unclear how the misuse of multiple medications would be lessened by restricting pharmacy formularies. It would seem that there might be better approaches to deal with that problem.

We also do not understand how the high discontinuation rates for antipsychotics means that there are multiple, equally good options for initiation of pharmacological therapy. From our perspective, this would lead to the opposite conclusion! For our patients, we see high discontinuation rates because there

are highly unique reactions to each of these individual medications. There are obvious genetic underpinnings to the metabolism of these drugs.[12] Different patients can tolerate and use effectively different ones of these drugs. As we do more pharmacogenomics testing in the field of psychiatry, we are now able to see that genetics can impact the tolerability or therapeutic effect for a particular medication for a patient. With pharmacogenomics testing, it can become very obvious why the first several drugs didn't work.

Your review panel cited as a reason for antipsychotics losing their protected status that they are noted to cause an increased risk of death in patients who have dementia-related psychosis and that they are prescribed within long term care facilities at an alarming rate. We agree that antipsychotics are overprescribed to older adults, that they can cause increased risk of death to patients with dementia, and that they are overprescribed in long term care facilities. However, we fail to see how restricting open coverage will do more than dictate *which* 2-3 antipsychotics will be improperly prescribed. Frankly, when looking at prescription patterns for antipsychotics over the past 10 years for the entire US population, one can see that there is a huge uptick in prescribing patterns for all ages, including children ages 0-5.[13, 14, 15, 16] This is very worrisome given the array of side effects for these very potent but very complex medications. However, this similar pattern of increased prescribing can be seen for other psychotropic medications, including ADHD and anxiety medications, which do not have protected status.[17, 18] It is clear that a better understanding of the causes of increased medications should be studied, rather than simply limited the medication choices to the experts who prescribe them. Exceptional behavior, i.e. over utilization of medications by some providers, should not be used to form poor public policy.

At Centerstone, the patients we serve are not in long term care. 80% of the people we serve are on Medicaid patients, and most of our patients that would be impacted by these regulations are "dually eligible," many of them disabled younger in life due to their mental health conditions (bipolar disorder, schizophrenia, among others). As you know, lifetime prevalence of schizophrenia is around 1.1% and bipolar disorder is 2.6% of the general population.[19] Persons with psychosis-related disorders are the sickest of the sick, and only a small subset receives minimally adequate treatment currently.[20] There are a variety of reasons for this lack of adequate treatment, and there are some excellent solutions that have been proposed to address this. We at Centerstone are trying to be part of the solution, working to improve the quality of care we provide through transparent outcomes tracking, utilization of analytics, and incorporation of research-based practices into care. However, we believe adding a restricted formulary for antipsychotics prescription is not part of the solution to improve care for persons with psychosis. We believe that this would actually harm our psychiatric staff's ability to provide the best psychiatric care possible to this fragile population.

While there are some protections talked about in the proposed regulations to aid with transition, these are not clearly laid out. We want to emphasize that forced switching of antipsychotic medications for persons with psychosis related disorders is extremely risky and potentially damaging. We believe that there would be a very real cost in human lives if we are forced to switch medications for people with psychosis related disorders who are reasonably stable. We believe that increased restrictions would result in increased hospitalizations and suicides. Every psychotic relapse, especially with a forced switch from a medication that worked to one that could not be tolerated due to side effects, impacts a person's ability to function, make it to his or her job, sustain relationships, avoid substance abuse, and fight suicidality. Psychoses do not just make people unable to be conscious of reality. They also harm brain functioning, leading to a

sometimes permanent loss in IQ. The dually eligible, the most frail of our patients, would be greatly impacted by these changes and might experience setbacks from which they could not recover.

Being unable to access a drug for these incredibly vulnerable patients after a reasonable number of antecedent trials does not make medical sense. From our perspective, there are already a limited number of choices available, all of which have serious side effects. Our medical staff need the flexibility to work with the patients to identify an antipsychotic that works for them and has side effects that are not intolerable for them. For a patient with Bipolar 1 disorder that is a singer for a living, extreme dry mouth is an intolerable side effect. For a patient who is at risk for diabetes and has prediabetes symptoms, he or she needs a medication with lower incidence of metabolic syndrome. To eliminate a full range of access to these medications, especially injectable medications for persons who, for a variety of reasons (from homelessness to cognitive deficits), cannot take daily medications, is very problematic. We believe that this will lead to a higher level of hospitalization for our patients. Since there are currently so few psychiatric inpatient beds available, we also believe that states would need to ramp up inpatient options. We believe if these changes go into effect, we are going to have fewer patients who have control over their conditions.

We very much appreciate your consideration of these comments. As you can see, we care deeply about ensuring our patients have access to the very best mental healthcare possible.

We strongly oppose this proposed aspect of the rule and respectfully request that in the final rule, antipsychotic medications retain their protected status in Medicare.

Thank you so very much for considering these suggestions. We appreciate your leadership in this matter, and we hope that you take these comments into account as you consider how to best care for the millions of Americans who depend on these medications.

Sincerely,

Jerry Neff, MD
Chief Medical Officer
Centerstone of Indiana

Karen Rhea, MD
Chief Medical Officer
Centerstone of Indiana

Suzanne Koesel, LCSW
Chief Executive Officer
Centerstone of Indiana

Bob Vero, Ed.D.
Chief Executive Officer
Centerstone of Tennessee

John G. Markley, MBA
Chief Executive Officer
Centerstone of Illinois

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Mrs. BLACKBURN. And I thank the gentleman for yielding the time, and I yield back the balance of my time.

Mr. PITTS. The Chair thanks the gentlelady. Now yields to the ranking member of the subcommittee, Mr. Pallone, 5 minutes for an opening statement.

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. Thank you, Chairman Pitts.

The Centers for Medicare & Medicaid Services, CMS, recently proposed program changes to the Part D Prescription Drug Benefit for 2015, and I believe it is important that we thoughtfully examine these changes, and the effects they will have on the program and on beneficiaries.

Unlike my Republican colleagues' tactics towards the Affordable Care Act, my initial opposition to the Part D law has not stopped me from working to improve and strengthen the program for seniors. In fact, the ACA took important steps to address the inadequacies that first caused me concern. Specifically, we closed the doughnut hole. So I welcome today's hearing so we can learn from the agency and other stakeholders about what is working and not working in the Part D Program, and, of course, how we can strengthen the program to work better for seniors and taxpayers alike.

Truthfully, it frustrates me that the Republicans are politicizing this issue using alarmists and exaggerated rhetoric to make a politically motivated point. Given the significance of the Medicare Program, I hope we can have a constructive and sincere discussion today on CMS' recent proposals regarding the Medicare Drug Benefit. The committee has a valuable function of monitoring and looking for ways to improve programs under its jurisdiction, however, let's not forget that CMS also plays a role in ensuring that its programs are working as effectively and efficiently as possible. One way it does this is by promulgating regulations to make adjustments, and respond to changes in the healthcare landscape and evolving needs. Importantly, part of the federal rule-making process involves making the proposed program changes available for public comment, and taking comments into consideration before finalizing the regulation.

Mr. Chairman, there are many positive provisions in this rule that, even if it is not perfect, I do not agree with the naysayers who have called for its dismissal outright. Rather, we should move forward on how best to achieve our objectives for a Part D program that serves its beneficiaries as best as possible. For example, the proposed rule seeks to make improvements to transparency, and to reducing fraud and abuse. These are issues I think we can all agree are important to continue to work on. I can also see the value in offering meaningful choices for beneficiaries, rather than just more choices, which create unnecessary complexity in making plan choices.

Now, there are some policies in this proposed rule that give me pause. In particular, the proposed Protected Classes policy. I think everyone here should share in the administration's goal of lowering

prices, but I do worry that the benefits to Medicare may not outweigh the risks when it comes to vulnerable patient populations.

So, Mr. Chairman, I just hope that today we can have meaningful discussion about these policies. I look forward to hearing from our witnesses about the rule, and how we can continue to improve and strengthen Part D.

I'd like to yield now the remainder of my time to Mr. Green, if he'd like.

OPENING STATEMENT OF HON. GENE GREEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. GREEN. Thank you. Thank you for yielding to me, and I want to thank the chairman and also the ranking member for having the hearing today.

Some of us were on the committee when we drafted the prescription drug plan, Medicare Part D, in 2003, and it was also a very partisan issue, just like the Affordable Care Act. In fact, in some of my emails over the years that said that the Affordable Care Act was passed at night, I really remember the vote being left open for about 6 hours, and I think our vote was about 5:00 a.m. in the morning, and my colleague from Illinois knows that. So even Congress can work at night sometimes on both issues. And I also recall that the Affordable Care Act had trouble rolling out. We actually worked with our constituents to help people use community college, community computers to help people access it, even though I considered the plan flawed. Although over the years there have been changes and a reform, mainly administrationwise, and I think that is what we are going to see today.

While it is clear that Part D programs provide prescription drugs for Medicare beneficiaries who previously didn't have it, there is still room to improve the program. And I have concerns about individual provisions in the proposed rule, but I support increased transparency and expanded access to affordable pharmacies, and cost sharing for Medicare beneficiaries.

And again, I thank my colleague for yielding the time, and I yield back.

Mr. PALLONE. And I yield back, Mr. Chairman.

Mr. PITTS. The Chair thanks the gentleman. Now recognize the vice chair of the subcommittee, Dr. Burgess, for 5 minutes for an opening statement.

OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BURGESS. I thank the chairman for the recognition. Mr. Blum, welcome to our committee today, and to our other witnesses, we are happy to hear from you.

So December of last year, the end of 2013, marked the 10-year anniversary of the creation of the Medicare Part D Prescription Drug Benefit. Not only has Part D come in at 45 percent under budget, the Congressional Budget Office has reduced its 10-year projections for Part D by over $100 billion for each of the last 3 years. The success of Part D is largely attributed to its competitive, free-market structure.

I would remind my friend from Texas that, different from the Affordable Care Act, the Part D changes were noncoercive and based on free-market principles, entirely different from the ACA.

So despite a proven track record of success, the Center for Medicare & Medicaid Services has proposed to fundamentally restructure the Part D Program; restructure it with a 700-page rule allowing the government to interfere in private plan negotiations, restrict beneficiary choice of plans, and limit incentives that lower costs for consumers. Only in Washington would there be a big government solution in search of a problem that simply does not exist.

The interference by the Centers for Medicare & Medicaid Services is projected to eliminate almost half of current Part D plans in 2015. So what effect will that have? Well, it is going to drive premiums higher for nearly 14 million seniors, and increase costs across the entire Medicare Program. Even more concerning is the proposal by the Centers for Medicare & Medicaid Services to eliminate several of the protected classes of drugs under Part D. We all remember when Dr. McClellan came to this committee, and the Democrats asked some pretty incisive questions, and Dr. McClellan was able to defend the Part D Program based on the fact that there would be these protected classes under Part D. They were designed to ensure that vulnerable populations of patients have continued access to lifesaving drugs. Not all drugs are interchangeable, especially in the case of immunosuppressants.

Without this committee getting into the pharmacology of how these drugs work, if we don't understand how they work, how can we change the policy so that—and not affect the patient at the same time? The removal of these drugs from protected class status risks the lives of current and future beneficiaries, further jeopardizing transplanted organs and patients' lives.

Yet again, the Centers for Medicare & Medicaid Services has proposed a policy that is penny wise and pound foolish. Not only has the program increased patient access to drugs, and made positive effects on the health of beneficiaries, the program has extended the solvency of the entire Medicare Program, saving billions of dollars over the past 10 years. So rather than continue a successful program and encourage innovation, now we are faced with a rule to ruin one of the only working parts of our current healthcare system, leaving patients with the short end of the stick.

I would like to submit for the record a statement by the National Kidney Foundation and the American Society of Transplant Surgeons. And yield to Mr. Shimkus.

Mr. PITTS. Without objection, so ordered.

[The information follows:]

National
Kidney
Foundation™

Statement by the National Kidney Foundation

Submitted to the Committee on Energy and Commerce
Subcommittee on Heath
U.S. House of Representatives

Hearing to Examine Proposed Changes to Medicare Part D
February 26, 2014

The National Kidney Foundation (NKF) thanks the Subcommittee for holding a hearing on the Administration's proposed changes to the Medicare Part D program, including the protected class status, and we appreciate the opportunity to share our concerns with you. NKF is America's largest and oldest health organization dedicated to the awareness, prevention and treatment of kidney disease for hundreds of thousands of healthcare professionals, millions of patients and their families, and tens of millions of people at risk. In addition, NKF has provided evidence-based clinical practice guidelines for all stages of chronic kidney disease (CKD), including transplantation since 1997 through the NKF Kidney Disease Outcomes Quality Initiative (NKF KDOQI).

Under the Centers for Medicare & Medicaid Services (CMS) proposed rule issued on January 6, 2014, immunosuppressive drugs for transplant recipients would no longer be included as a protected class under Medicare Part D. This decision risks transplant physicians' ability to prescribe the drug regimen most appropriate for their individual patients. Immunosuppressants are prescribed in combinations tailored to meet the unique needs of the individual transplant recipient in order to achieve sufficient immunosuppression while minimizing the toxicity associated with individual agents. Kidney recipients must take immunosuppressive drug indefinitely to prevent organ failure. Consultation with our transplant physician members and our organ recipient members further underscores the need for all immunosuppressive drugs to be available on health plans formularies. Identifying the most appropriate immunosuppressive combination often requires fine tuning. Clinical guidelines support transplant physicians in identifying the combination with the strongest evidence base, but requires the expertise of the physician who knows the medical history of the patient to tailor the best regimen. Typically patients receive a tailored combination of drugs immediately after transplant (the induction phase) and then have another combination tailored for them for the long-term (the maintenance phase). Recipients require close monitoring after a new combination is prescribed to ensure it will sufficiently suppress the immune system and protect the organ, while minimizing the adverse side-effects. This delicate balance was recognized in the original decision to include these medications under protected status.

The CMS proposed rule referenced a report from a panel the agency had engaged to evaluate the new criteria against the current protected classes. The panel referenced only 2009 clinical guidelines for the Long-Term Treatment of the Liver Transplant Patient in its decision to remove protections for immunosuppressant. The panel appears to have incorrectly concluded that a more specific formulary that ensures only each *subclass* of immunosuppressive drugs is available would suffice for the treatment of all transplant recipients. However, the drugs under each subclass are not interchangeable. Any drug in a subclass may have a different mechanism of action providing a very different level of benefit, or, in a worst case scenario, may be more neurotoxic to a specific patient than another drug. NKF firmly believes patient access to *all* immunosuppressive drugs within each subclass must be maintained to provide optimal patient care.

Since the release of the proposed rule, NKF has heard from many of our patients about how difficult it was for their physician to identify the most appropriate and beneficial immunosuppressive therapy. Often, the first prescribed drug combination needs to be adjusted or replaced. Patients who have contacted us are terrified they will lose access to the specific drugs that best meet their needs. We have also heard from these patients that today they are stable and doing well on their immunosuppressive regimen. While CMS has recognized that subjecting transplant recipients to a lengthy appeals process would put patients' lives and organs at risk, the agency has not provided guidance as to how it will make sure patients are able to quickly access the combination of medications prescribed to them by their physician if immunosuppressants are no longer a protected class. Instead, this proposed rule risks the stability thousands of current patients have achieved with their current immunosuppressive regimen and limits physicians' ability to tailor regimens for new recipients. The proposed rule also sends the signal to other private insurance plans that it is ok to limit patient access to immunosuppressive drugs on their formularies, putting even more transplant recipients at risk.

This is not the way to achieve Medicare savings and in fact it could result in higher costs through an increase in hospitalizations or even failed organ transplants. With more than 120,000 Americans on organ transplant waiting lists and fewer than 27,000 transplants performed last year, policymakers must do everything possible to maintain the viability of the transplanted organ. We urge Congress to prevent the Administration from changing protected class status for immunosuppressive drugs and maintain patients' access to all immunosuppressants under Medicare Part D.

Thank you for your consideration and the opportunity to share our concerns.

ASTS
American Society of Transplant Surgeons

TESTIMONY SUBMITTED FOR THE RECORD

AMERICAN SOCIETY OF TRANSPLANT SURGEONS (ASTS)

TO THE
HOUSE COMMITTEE ON ENERGY AND COMMERCE
SUBCOMMITTEE ON HEALTH

"MESSING WITH SUCCESS: HOW CMS' ATTACK ON THE PART D PROGRAM WILL INCREASE COSTS AND REDUCE CHOICES FOR SENIORS"

WEDNESDAY, FEBRUARY 26, 2014 - 10:00AM

Chairman Pitts and Ranking Member Pallone, on behalf of the American Society of Transplant Surgeons (ASTS), thank you for the opportunity to submit written comments on today's hearing entitled, "Messing with Success: How CMS' Attack on the Part D Program Will Increase Costs and Reduce Choices for Seniors."

ASTS objects in the strongest possible terms to the proposal published by the Centers for Medicare and Medicaid Services (CMS) on Monday, January 6, 2014, to remove immunosuppressants from the list of six protected classes of drugs under Medicare Part D, effective in 2015 (the "Proposed Rule"). ASTS is an organization composed of more than 1800 transplant surgeons, physicians, and scientists dedicated to excellence in transplantation surgery through education and research with respect to all aspects of organ donation and transplantation so as to save lives and enhance the quality of life of patients with end stage organ failure.

Current policy ensures that transplant recipients have access to the most appropriate immunosuppressants by prohibiting Part D plans from restricting access through formularies. The Proposed Rule would enable Part D sponsors to impose formulary restrictions on these critical drugs, resulting in substantial risk of rejection, serious side effects, and other adverse drug reactions for Medicare Part D beneficiaries who are transplant recipients.

Background: Medicare Part D Coverage of Immunosuppressants

Immunosuppressant drugs are covered under Part B provided they are used in immunosuppressive therapy by a beneficiary who received a transplant covered under Medicare Part A. In all other situations, these drugs are covered under Part D. In 2007, 74,000 beneficiaries took immunosuppressants under Part B, and more than 80,000 beneficiaries took immunosuppressants under Part D.

History of the Six Protected Classes Rule

The Medicare Modernization Act (MMA) created the Medicare Part D drug program in 2003, and when CMS implemented the program, Congress urged the agency to cover "*all or substantially all*" medications within certain protected classes. As a result, CMS issued sub-regulatory guidance identifying six classes and

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categories of drugs (including immunosuppressants) that would not be subject to formulary restriction. Due to uneven implementation of this informal guidance, Congress enacted Section 176 of the Medicare Improvements for Patients and Providers Act (MIPPA), which established statutory protection for immunosuppressants and five other protected classes of drugs under Medicare Part D by requiring Medicare Part D drug plans to include in their formularies access to *all or substantially all* drugs in the six identified classes.

It is against this backdrop that the Affordable Care Act (ACA) provided CMS with authority to develop criteria to "identify, as appropriate, categories and classes of drugs for which the Secretary determines are of clinical concern." As such, Congress codified protected class status for immunosuppressants and the other five pre-existing protected classes of drugs and expanded protected status to *all* drugs within these six classes, although this codification is subject to the pending rulemaking.

The Proposed Regulation

The Proposed Rule proposes to withdraw protected status for three of the current six protected classes of drugs, including immunosuppressants. In so doing, the Proposed Rule sets forth extremely stringent criteria for a drug class or category to meet in order to obtain or retain protected status. Under the Proposed Rule, a class or category of medication must meet both of the following standards to retain or obtain protected status:

- For a "typical individual," hospitalization, persistent or significant disability or incapacity, or death likely will result if initial administration (including self-administration) of a drug in the category or class does not occur within 7 days of the date the prescription for the drug was presented to the pharmacy to be filled; **and**
- More specific CMS formulary requirements will not suffice to meet the universe of clinical drug-and-disease-specific applications due to the diversity of disease or condition manifestations and associated specificity or variability of drug therapies necessary to treat such manifestations."

In the Proposed Rule, CMS indicates that immunosuppressants meet the first of these standards but not the second. For this reason, CMS proposes to withdraw protected class status for immunosuppressants, thereby facilitating the imposition of formulary restrictions on transplant recipients' access to these critical drugs. With the changes proposed by CMS, access to immunosuppressants could be limited to only two medications in each class and category.

The sole rationale provided in the Proposed Rule for establishing such narrow criteria for protected class status and to so substantially modify longstanding Medicare policy is that, because drug manufacturers understand that formulary restrictions may not be imposed on medications that fall within the protected classes, they are generally unwilling to provide substantial discounts to Part D plans for these drugs. The Proposed Rule fails to discuss or otherwise take into account the potential for substantial increases in Part A or Part B costs in the event that inadequate immunosuppression results in organ rejection, hospitalization, or other adverse health consequences for Medicare Part D beneficiaries. Nor does the Proposed Rule explain the agency's reversal of its prior position that access to all or substantially all immunosuppressants is necessary due to the complexity of immunosuppressive regimens, the severity of the health consequences in the event that immunosuppression is ineffective, and variation in individual response.

ASTS Observations

The ASTS strongly urges Congress to join us in asking CMS to refrain from authorizing Part D plans to impose formulary restrictions on Medicare patients' access to critical immunosuppressants.

Immunosuppressants unequivocally meet both of the standards set forth for protected class status in the Proposed Rule. Moreover, allowing the imposition of formulary restrictions on the immunosuppressants available to Part D beneficiaries has the potential to result in dire health consequences for individual enrollees; to exacerbate an already critical organ shortage; to result in additional confusion and medication non-adherence; and to establish unjustified distinctions in coverage between Part D beneficiaries and those covered under Part B or private plans. In addition, authorizing such formulary restrictions has the potential to significantly increase, rather than decrease, overall patient and program costs.

Immunosuppressants Meet Both of the Proposed Standards for Inclusion in a Protected Class

CMS correctly determined that immunosuppressants meet the first of the two standards proposed for inclusion of a drug class or category in a protected class: We most certainly concur that the first standard is met. Indeed, significant health consequences result if immunosuppression is not instituted within seven days of a prescription. However, CMS' determination errs in concluding that immunosuppressants fail to meet the second of the two proposed standards. In fact, there is a critical need for physicians to have the flexibility to individualize immunosuppressant therapy, both to protect against rejection and to minimize potentially serious side effects. Because individual patient response to various immunosuppressants is idiosyncratic and cannot be predicted, it is impossible for CMS to impose formulary requirements without unreasonably restricting access to those drugs that may be critical for individual patients.

CMS' conclusion that transplant surgeons do not need access to the full panoply of immunosuppressants to individualize therapy and ensure against rejection is based solely on the determination of a panel of CMS pharmacists and the CMS Chief Medical Examiner. It does not appear that the panel of pharmacists involved includes transplant pharmacists, nor does it appear that transplant physicians or surgeons participated in the panel deliberations. The Proposed Rule indicates that, because widely accepted treatment guidelines recommend subclasses of drugs rather than specific, individual drugs, the panel did not believe that every drug product should be required for inclusion on Part D sponsors' formularies.

Conversely, and quite inconsistently, CMS insists that the relevant treatment guidelines are sufficiently detailed to enable the agency to establish "additional, specific formulary requirements" without needing to require that Part D sponsors make all or substantially all immunosuppressants available to Medicare Part D beneficiaries.

CMS' rationale for concluding that immunosuppressants do not meet the second of its proposed "protected class" criteria is unsupportable for several reasons. First, the panel specifically references only a single guideline, the 2009 treatment guidelines for the Long-Term Treatment of the Liver Transplant Patient, and notes that this guideline does not recommend specific drugs within each of the classes over any other in the same class. The panel concludes that CMS' current formulary review requirements based on treatment guidelines would capture immunosuppressants in all the classes of drugs delineated in the guideline, and, on this basis, the panel concludes the current beneficiary protections are sufficient.

Unfortunately, the panel draws an incorrect conclusion based on its review: While this guideline does outline recommended immunosuppressant therapy in terms of the classes of drugs generally included in an effective immunosuppressant regimen, this guideline does not suggest or imply that individuation of immunosuppressive regimens within these classes is not required. In fact, it is precisely because different recipients react differently to the drugs within each class that specific drugs are not recommended by the guideline. The same is true of other treatment guidelines that specify the recommended immunosuppressive regimen in terms of the classes of drugs and not in terms of specific named immunosuppressants.

Second, in fact, the need to individualize immunosuppressants to meet individual patient needs is well recognized in the clinical literature, in clinical guidelines, and in the statements of professional associations. Immunosuppressive medications are not interchangeable. They are prescribed in combinations tailored to meet the unique needs of the individual transplant recipient in order to achieve sufficient immunosuppression while minimizing the toxicity associated with individual agents. Restrictive formularies limit physicians' ability to prescribe the right combination of medications to protect the recipient from organ rejection and other serious side effects. This delicate balance was recognized in the original decision to include these medications under protected status.

Transplant physicians devote a significant portion of their training to learning the nuances of recipient-centered immunosuppression. A major focus of transplant physicians' attention to transplant recipients is dedicated to individualizing the post-transplant immunosuppressive regimen. One of the largest areas of transplant research is directed toward comparison of different immunosuppressive drugs and regimens. All of these efforts are based on the need to prolong transplant graft survival and to decrease the multitude of life-threatening side effects caused by immunosuppressive agents. Each patient has a unique risk for rejection and for untoward effects of immunosuppressive drugs. Access to all available drugs permits choice of a regimen that minimizes side effects such as renal failure, diabetes, hypertension, hyperlipidemia, neurotoxicity, bone marrow suppression, gastrointestinal toxicity, and others. It is precisely such access to a growing number of immunosuppressive agents and attention to individualizing regimens for each patient that has been a major contributor to improved transplant organ and patient survival. Any barrier to nuanced immunosuppression will lead to worse patient outcomes.

Third, it is unclear how CMS can reasonably and simultaneously conclude that BOTH (1) the recommended protocols for immunosuppression are so general that they "only recommend subclasses of drugs rather than specific individual drugs" AND (2) that these very same protocols are sufficiently detailed for the agency to formulate "additional specific formulary requirements" that are sufficient to account for individual variation among transplant recipients. In fact, it is precisely because individual reaction to immunosuppressants is virtually impossible to predict that applicable treatment guidelines do not specify individual drugs but rather formulate recommendations in terms of drug classes and sub-classes. It is extremely difficult for us to understand how CMS can formulate "additional, specific formulary requirements" when those expert in the field, including highly trained and experienced transplant pharmacists, physicians, and surgeons, have concluded that it would be unreasonable to do so in the face of the vast variation in transplant recipients' reactions to the array of immunosuppressive agents currently available.

Limiting Access to the Full Range of Immunosuppressants Available to Transplant Recipients Has the Potential to Endanger Patients

CMS' Proposed Rule appears to be premised on the assumption that transparency, appeals, and other Part D protections are sufficient to ensure that the imposition of formulary restrictions on the availability of immunosuppressants will not increase organ rejection or otherwise endanger Medicare beneficiaries. We strongly disagree. In fact, finalizing the Proposed Rule in its current form holds substantial risk for highly vulnerable transplant recipients covered under Medicare Part D.

Inadequate immunosuppression causes organ rejection, subsequent need for risky treatments, often transplant organ loss, and sometimes patient death. Contrary to CMS' assertions, current transparency, appeal, and other procedural requirements are not sufficient to ensure Medicare beneficiary access to individualized immunosuppressant regimens in the face of formulary restrictions. The CMS appeals process generally available to Medicare beneficiaries under Parts A and B is undeniably broken, and, while Part D appeals are generally resolved a bit more expeditiously, it is our understanding that most cases are not

heard within the 10 days required by Medicare rules. Eliminating protected status not only for immunosuppressants but also for far more frequently used anti-depressants and anti-psychotics would unquestionably swamp the already beleaguered appeals system, and appeals filed by the (relatively few) Medicare Part D transplant recipients likely would be lost in the quagmire.

In fact, limiting access to immunosuppressants based on formulary restrictions would further complicate the already formidable task of managing complex post-transplant immunosuppression regimens. In 2007, the Government Accountability Office (GAO) found that the percentage of beneficiaries whose kidney transplants failed roughly doubled when increasing the timeframe from 36 months following the transplant to seven years. GAO notes in its report:

> (w)hile a lack of health insurance is one reason transplant recipients may stop taking their medication, studies have reported that there are numerous other reasons for medication noncompliance, including avoidance of adverse side effects associated with immunosuppressive medications and difficulty following complex treatment regimens.

Placing further obstacles in the path of elderly transplant recipients covered under Part D by imposing formulary restrictions on critical immunosuppressants unnecessarily increases the risk of life-threatening organ rejection. In fact, it is unclear whether even the current protected classification of immunosuppressants is sufficient to ensure Medicare beneficiary access to all or substantially all of these critical drugs. According to CMS policy, all drugs in the immunosuppressant category, used to prevent organ rejection after transplants, are required to be covered by Part D plans unless a plan sponsor appeals to use a different categorization or makes a case to cover less than all of the drugs in this protected class. Yet, according to a recent Congressional Research Service analysis, on average, drugs in this class are covered by only 85% of plans. Most notably, the anti-thymocyte globulins in this class, Atgam and Thymoglobulin, are covered by fewer than half the plans. We respectfully urge CMS to refuse to give Part D plans even more flexibility to deprive transplant recipients of access to individualized and maximally effective immunosuppressive regimens, when many of these plans apparently have already failed to comply with regulatory requirements in this area.

The relatively recent availability of a number of important generic immunosuppressants further suggests that this is not the time to facilitate the imposition of formulary restrictions on immunosuppressants. From the approval of the first generic MMF and TAC in July 2008 and August 2009, respectively, through 2012, ten generic manufacturers of MMF and four generic manufacturers of TAC emerged. The use of generic immunosuppressants has grown steadily and substantially since they became available, and the use of generics is now substantial.

Widespread availability of generics has the potential to substantially decrease the cost of immunosuppression both for payers and for patients, undermining the need to withdraw protected status for these drugs to achieve cost savings. Moreover, the relatively rapid increase in the number of generic products available has increased patient and provider confusion, and clinical repercussions of switching to and among various generics has not been studied in depth. The issues related to generic substitution may be compounded by the impact of multiple switches between generic formulations due, in part, to insurance coverage arrangements. Further, monitoring of patient reaction to such switches is difficult since, under current generic substitution practices, the transplant team may not be notified that a patient's immunosuppressant has been switched to a generic, or switched from one generic to another. Patient confusion has been linked to decreased patient adherence,[1] and patient adherence is critical in preventing

[1] Journal of Transplantation, Volume 2013 (2013), article ID 897434; http://www.hindawi.com/journals/jtrans/2013/897434/#B14.

organ rejection. In short, the imposition of formulary restrictions on the availability of specific immunosuppressants by various Part D plan sponsors would substantially complicate effective immunosuppression for a vulnerable patient population during a time of significant transition and rapid advancements in drug therapy in the field of immunosuppression.

Imposing Formulary Restrictions Likely to Increase, Rather than Decrease, Medicare Costs.
Not only does the imposition of formulary limitations on immunosuppressants have the potential to increase the risk of organ rejection and other complications, it has the potential to increase, rather than reduce, overall program and patient costs for the Medicare program.

First, if this policy contributes to rejection of even a limited number of organs, the increased system costs would be substantial: In 2010, The United States Renal Data System (USRDS) estimated annual per beneficiary Medicare expenditures in 2010 to be $87,561 for a beneficiary receiving hemodialysis (the most common form of dialysis treatment) and $32,914 for a beneficiary with a functioning kidney transplant.

Second, there are numerous other mechanisms built in to Part D that have the potential to limit costs without impeding access to these critically important drugs. Immunosuppressive drugs are already subject to pre-approval requirements and "tiering": For example, one recent study indicated that two drugs in this class, Zenapax and Thymoglobulin, are on a specialty tier in two-thirds of the plans that cover them, and a number of common immunosuppressants are frequently subject to prior authorization.

Third, it is unclear whether the cost of immunosuppressants under Part D is substantially out of line. According to the USRDS, in 2010, Medicare expenditures for Part B immunosuppressive drugs were $4,008 per transplant recipient. [2] Only four expensive immunosuppressants have differences of more than $2,000 between annual Part B and Part D beneficiary spending: Thymoglobulin, oral Prograf, Cellcept, and oral cyclosporine. The difference between the total price in Part B and the total price in Part D is smaller for these drugs than for other high price drugs, such as hormonal suppressants, and the three branded products all have Part D prices within 20% of the Part B price.

Other Public Policy Considerations Support Retaining Immunosuppressants in the Protected Class
The imposition of formulary restrictions on immunosuppressants has the potential to result in unsupportable distinctions in the coverage afforded to Medicare beneficiaries under Part D and other transplant recipients. Under the Proposed Rule, Medicare Part D beneficiaries potentially would have much more limited access to immunosuppressant therapy than those insured under the state exchanges. For example, Medicare formulary rules would enable Part D sponsors to offer only two immunosuppressants in each class or subclass. Based on the preliminary 2012 EHB-benchmark plan designs across all states, each state would require health plans offered in the exchanges to cover drugs in the "immunosuppressive agent" classes. Roughly half of all states would require at least 20 different immunosuppressive drug products to be covered in health plans offered through their state's health insurance exchanges. The total number of drug products in the immunosuppressive agent class may not be much larger than 20, which may suggest that, if CMS' current formulary rules were applied, Part D plans would be authorized to limit access to immunosuppressants more severely than roughly half the state exchanges.[3]

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[2] US Renal Data System, *USRDS 2012 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States*, Bethesda, MD, 2012, Table K.b, http://www.usrds.org/reference.aspx. This figure is for individuals with Medicare as a primary payer only.

[3] For more information on the EHB prescription drug coverage methodology, see http://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/ehb-rx-crosswalk.pdf. An estimate of the total numbers of immune suppressant drug products available is 21. This estimate was gathered from the CMS Formulary Reference File Alignment File by grouping unique identifiers (RXCUIs) with the same active ingredient

Moreover, under the Proposed Rule, Medicare beneficiaries covered under Part D would have considerably more limited access to immunosuppressants than those covered under Part B. Under current law, immunosuppression is covered under Medicare Part B if the initial transplant was covered by Medicare in a Medicare-approved facility; while Medicare Part D covers immunosuppressive drugs for those Medicare beneficiaries whose initial transplant was not covered by Medicare. It clearly makes no sense to provide more limited flexibility in immunosuppressive regimen for some Medicare beneficiaries than for others, based solely on whether the initial transplant was covered by Medicare. Furthermore, such a policy would foreclose any future administrative efforts to consolidate coverage for immunosuppression under one of the two programs.

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For all these reasons, ASTS strongly urges CMS to refrain from finalizing the Proposed Rule and to retain immunosuppressants as one of the protected classes of drugs under Medicare Part D: Immunosuppressants do in fact meet the two "protected class" criteria proposed by CMS; allowing formulary restrictions has the potential to endanger Medicare Part D beneficiaries who are transplant recipients and to increase costs; and the current formulary review process used by CMS has the potential to result in less access to critical immunosuppressants for Medicare Part D beneficiaries than for recipients who obtain coverage through the state exchanges or under Medicare Part B. We strongly urge CMS to reconsider this counterproductive and potentially dangerous proposal.

Sincerely yours,

Alan N. Langnas, DO
President

David J. Reich, MD
Chair, Legislative Committee

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OPENING STATEMENT OF HON. JOHN SHIMKUS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Mr. SHIMKUS. Thank you. And I thank my colleague and friend.

More than 250 organizations united for a common goal, protecting seniors and individuals with disabilities from harmful changes to Medicare Part D. And that is what your proposed rule actually does, is harm seniors. It gives them less choices, it will project higher costs, and from an administration that cut $716 billion out of Medicare, to propose a 700-page rule trying to fix something that is not broken, is disastrous at a time when people are paying more, even in the national healthcare rollout.

It is safe to say when I go to my district, people pay more now for their insurance and get less, and this is just going to fall down to our seniors.

I also want to focus on the fact that Medicare Part D has been successful. I want to focus on medical therapy management issues, that moving that level down that small is just going to hurt medical therapy management for those bigger populations that actually need the care.

And I yield the rest of my time to Dr. Cassidy.

OPENING STATEMENT OF HON. BILL CASSIDY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF LOUISIANA

Mr. CASSIDY. Thank you.

I am a doc, and so when I talk to constituents back home about how changes by Obamacare and this administration are going to decrease their choices and increase their costs, I understand the issue.

Medicare was cut $716 billion to fund Obamacare, and frankly, when you cut that much, it has got to give. It is going to force beneficiaries to find new healthcare plans, despite the President's promise that you could keep your health insurance if you like it, period. Instead, they get cancellation notices.

Now, the Medicare cut $300 billion, or to the Medicare Advantage Program, and now I understand that—for—there is a further 3.55 percent cut on top of the cumulative 6.5 percent cut that the industry has already suffered. It is a very popular program. If you cut funding, seniors have less choice and increased cost.

Moving forward, we must preserve that and decrease those costs. We need policies that help seniors, not threaten access and choice.

I look forward to the questioning. Thank you. I yield back.

Mr. PITTS. The Chair thanks the gentleman and seeks unanimous consent to enter into the record the letter from Sixty-Plus Association.

Without objection, so ordered.

[The information follows:]

The 60 Plus Association

515 King Street • Suite 315 • Alexandria, VA 22314
Phone 703.807.2070 • Fax 703.807.2073 • www.60Plus.org

Kill the Death Tax. Protect Social Security and Medicare. Energy Security.

February 26, 2014

Dear Chairman Pitts:

On behalf of more than seven million senior citizen activists, the 60 Plus Association thanks the Subcommmittee on Health for holding this hearing on "Messing with Success: How CMS' Attack on the Part D Program Will Increase Costs and Reduce Choices for Seniors."

Policy successes in Washington are few and far between these days, so more than ever we pray that our leaders follow the old adage, "If it ain't broke, don't fix it."

The proposed rule issued by the Centers for Medicare and Medicaid Services (CMS) on January 6, 2014 will destroy the one health care program that has proven extremely effective in controlling prescription drug costs, has near unanimous satisfaction among seniors and is currently coming in 45% *under* its projected budget. Oh, and the current program offers a model of reform that could save our nation from financial ruin.

I am, of course, referring to the Medicare Part D prescription drug benefit, and no, that 45%-under-budget figure is not a typo. Passed under George W. Bush and a Republican Congress, Medicare Part D is performing astoundingly well. Seniors now have access to prescription drugs at an affordable monthly premium that has averaged $30 for three straight years without increasing. And more seniors taking prescriptions and thus staying healthier lowered Medicare's hospital costs by $13.4 billion in the first year alone — not a bad side effect.

The success of Medicare Part D's free-market competition and patient choice model shines light on a pathway to real and lasting reform that could keep Medicare solvent for generations to come. As Medicare stands now, the program will face shortfalls in funding in nine years or less. The $716 billion cut from Medicare to pay for Obamacare will further cripple the program.

Instead of embracing the reforms that have led to Part D's stunning success, The CMS' proposal will undermine it with a price-control scheme in the form of a "soak the rich" tax on health care providers. We all know that tax will be passed on to seniors in the form of higher premiums and co-pays. Call it the "politics of spite." Anything that empowers individuals and actually works is bad by Obamacare's meter. Anything the government controls is by definition good. By rejecting reform and doubling down on the failed models of the past, Obamacare is speeding our nation toward bankruptcy. It's absolute madness.

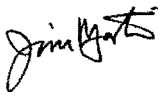
(over)

Seniors lost the benefits of competition and choice when Obamacare cut hundreds of billions from Medicare Advantage, the market-based program through which many seniors have chosen to receive Medicare benefits. Medicare Advantage is working to control costs and one out of four seniors has chosen it. Obamacare's cuts will result in millions of seniors losing Medicare Advantage, with those staying having to pay higher premiums and co-pays.

This call for price controls on the drug industry will be equally disastrous. In addition to higher premiums and less choice, seniors will see less research and development to find the lifesaving cures of the future. Drug costs are already being held down by the healthy competition Medicare Part D provides. Injecting price controls like those in the failed Medicaid program, where costs keep rising and doctors are less and less willing to serve patients, is not in the interest of seniors. Unfortunately, if this proposed rule goes through, it will destroy reform, choice and innovation in order to strengthen the government's grip on health care.

Our nation's seniors were vocal champions of Medicare Part D in last year's national election because it has proven that free-market reforms work and can help cure our health care and budgetary ills. The CMS should acknowledge the success of Part D instead of attempting to undermine it. If the CMS truly cared about seniors and strengthening Medicare for future retirees, it would build on this model of reform and quit trying to fix the one thing in Washington that "ain't broke."

Sincerely,



Chairman

Mr. PITTS. The Chair now recognizes the ranking member of the full committee, Mr. Waxman, 5 minutes for an opening statement.

OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. WAXMAN. Thank you, Mr. Chairman.

Today's hearing will focus on the Medicare Part D drug program.

When President Bush signed the Part D benefit into law, Democrats had many concerns. We thought the structure of the law was too confusing for beneficiaries, we thought the doughnut hole was bad for seniors, and we felt the law did not do enough to reduce drug costs, and most of us voted against it. But, Mr. Chairman, we didn't find dozens of ways to sabotage the program. We didn't send out massive document requests in order to delay and intimidate contractors. We didn't shut down the government to try to force its repeal, or vote over 40 times to repeal the law. Instead, we worked with the Bush administration to make sure our constituents could get the benefits they deserved, and ultimately, as part of the Affordable Care Act, we improved benefits, closing the Part D doughnut hole.

Mr. Chairman, your constituents and the Nation would be much better off if your party took a similar approach to the Affordable Care Act.

We improved the Part D law, but there are still adjustments we can make to strengthen the program for both beneficiaries and taxpayers, improving transparency and addressing fraud and abuse.

CMS recently proposed a rule that would make some of these changes. I appreciate the agency's efforts. They show that the administration continues to work to improve Medicare for seniors.

The proposed Part D rule provisions would increase transparency, and increase access to community pharmacy services. Many community pharmacies have been unable to participate in Part D plan's preferred networks, even if they are willing to meet the plan's preferred prices. CMS proposes to allow any pharmacy who can meet the plan's prices to participate. This change would increase pharmacy access for patients, particularly in underserved communities where patients may not have access to preferred pharmacies.

CMS has also proposed simplifying beneficiary choices under Part D. CMS and patient advocates have long noted that seniors find the array of plan choices dizzying, and that plans are using the multitude of choices to segment risks and maximize profit. It makes sense for both the patient and the taxpayer that CMS address these matters.

There are other places where I would like to see the agency rethink its approach. In particular, the Six Protected Classes policy. I share the administration's goal of lowering prices, and ensuring that Medicare is able to get the best deal possible. CMS has correctly observed that eliminating some drugs from the Protected Classes category would allow Part D plans to negotiate for lower prices, but it is hard to ignore the concerns of patient groups and Medicare advocates that these changes will make it more difficult for seniors to get the drugs they need.

There is a better way. Adopting my Part D Drug Rebate Bill, the Medicare Drug Savings Act would be a much sounder and beneficiary-friendly approach. This bill would allow Part D to get some discounts on drugs for low-income seniors that Medicaid and private sector purchasers receive. It would, according to the CBO, save over $140 billion over the next decade.

The administration was correct to include this provision in its new budget. It is a commonsense idea that would save taxpayers billions of dollars without affecting access to Part D drugs for seniors.

Mr. Chairman, I am pleased that Deputy Administrator John Blum is here today to explain CMS' approach in the Part D rule. I look forward to discussing how we can improve Part D for seniors, and reduce taxpayers' costs, and yield back the balance of my time.

Mr. PITTS. The Chair thanks the gentleman, and again seeks unanimous consent to enter a letter to Administrator Tavenner from a coalition of 250 organizations on Medicare Part D.

Without objection, so ordered.

[The information follows:]

March 7, 2014

The Honorable Marilyn B. Tavenner, Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-4159-P
P.O. Box 8013
Baltimore, MD 21244-8013

Dear Administrator Tavenner:

Thank you for the opportunity to share our views on CMS's proposed changes to the Medicare Part D prescription drug program. The undersigned organizations reflect a wide breadth of companies and organizations representing, among others, multiple healthcare sectors, employers and patients that share your commitment to a strong Medicare that meets the healthcare needs of its beneficiaries.

We are deeply concerned that the proposed rule is inconsistent with the spirit and purpose of Medicare Part D, represents unnecessary changes to programs that are already extraordinarily effective in containing costs and, most importantly, will severely impede beneficiaries' access to affordable health plans and medicines. We urge you in the strongest terms to withdraw the proposed rule that would have unintended consequences for seniors and beneficiaries with disabilities.

As you know, Medicare Part D is an undeniable success story. The Part D program has maintained stable, affordable average monthly premiums, enjoys a 90 percent approval rating among beneficiaries, and has program costs that are more than 40 percent below original Congressional Budget Office projections.

The proposed rule threatens to disrupt the positive effect the program is having on beneficiaries' health and the Medicare program as a whole. Each undersigned organization has concerns about specific provisions, but there are overarching issues on which we are unanimous in our objections.

First, the rule would significantly reduce beneficiaries' choice of plans and medicines and lead to disruptions in care. Millions of seniors and beneficiaries with disabilities would lose their current plan of choice or face changes in coverage. Beneficiaries value choice in the Part D marketplaces, and a range of options promotes both competition and innovation in benefit designs that improve the way beneficiaries' access their Part D benefits and services.

Second, it would fundamentally transform the market-based competitive models that have made the Part D program highly successful. The rule would dramatically expand the federal government's role in Medicare Part D despite the fact that there is no compelling reason for doing so. Reshaping Part D in this way will neither improve quality and affordability, nor incentivize plan innovation.

Third, the proposed regulation will impose a large cost burden that will impede the ability of plan sponsors and other health sectors to continue offering affordable, quality care to patients. These new costs will drive higher premiums for millions of beneficiaries and lead to higher costs for Medicare without tangible gains in service or quality for beneficiaries.

And, finally, the timing of this omnibus proposed rule has created great uncertainty as many of our organizations and the companies we represent have already begun preparations for the 2015 plan year. Many of these organizations are also currently devoting significant resources to ensuring the success of the health insurance exchanges, and this would represent a tremendous additional burden. With the June bid submission deadline in mind, we urge you to withdraw the proposed rule in a timely manner in order to minimize disruption for beneficiaries when it comes time to make plan selections in October.

In summary, the Part D proposed rule will not only fail to achieve its intended goals but will reduce choice and impose higher costs on beneficiaries and taxpayers. Medicare Part D has succeeded beyond expectations in enhancing the health and well-being of enrollees. Weakening these programs will result in a less healthy patient population and, consequently, increased Medicare costs in the long term.

Consequently, we urge CMS to withdraw the proposed rule that, as written, would fundamentally undermine the success of the Part D program for beneficiaries. We look forward to working with you to assure that Medicare continues to offer affordable, high-quality health coverage and accessible medications. It is a privilege to work with you to meet the needs of current and future Medicare beneficiaries.

Sincerely,

Abcam Inc
Academy of Managed Care Pharmacy
Addario Lung Cancer Foundation
Advocates for Responsible Care (ARxC)
Aetna
AIDS Alliance
AIDS Connecticut (ACT)
AIDS Delaware
AIDS Services for the Monadnock Region
Allergan
Alliance for Paired Donation
Alliance for Patient Access
Alzheimer's and Dementia Resource Center
Alzheimer's & Dementia Alliance of Wisconsin
Alzheimer's Arkansas
Amada Senior Care
America's Health Insurance Plans
American Autoimmune Related Diseases Association (AARDA)
American Dental Association
American Kidney Fund
American Osteopathic Association
American Society of Plastic Surgeons
Amgen
Analtech, Inc.
Arizona Bioindustry Association, Inc. (AZBio)
Arizona Urological Society
Arkansas Psychiatric Society
Association of Black Cardiologists
Association of Community Cancer Centers

Asthma and Allergy Foundation of America
Asthma and Allergy Foundation of America, New England Chapter
Atlanta Black Nurses Association
BayBio
Bio Nebraska Life Sciences Association
Biocom
BioForward
BioHouston
BioNJ
BioOhio
Bioscience Association of West Virginia
Biotechnology Industry Organization
Bismarck-Mandan Chamber
BlueCross BlueShield Association
Boehringer Ingelheim Pharmaceuticals, Inc.
California Asian Pacific Chamber of Commerce (CalAsian Chamber)
California Healthcare Institute (CHI)
California Hepatitis C Task Force
California Senior Advocates League
California Urological Association
Cancer Support Community Central Ohio
Capitol Insurance Brokers, Inc.
Caregiver Action Network
Cascade AIDS Project (CAP)
Catamaran
Center for Lawful Access and Abuse Deterrence (CLAAD)
Center for Medicine in the Public Interest
Centerstone
Central Florida Behavioral Health Network
Central New York HIV Care Network
Centro de Mi Salud, LLC
CETPA, Inc.
Chemistry Council of New Jersey
Cigna
Citrus Council, National Kidney Foundation of Florida
Coalition of Texans with Disabilities
Colon Cancer Alliance
Colorado BioScience Association
Colorado Cross-Disability Coalition
Colorado Gerontological Society
Colorado State Grange
Combined Health Agencies
Community Access National Network (CANN)
Community Health Action Network (CHAN)
Community Health Charities of Iowa
Community Health Charities of Nebraska
Community Health Charities of Wisconsin
Community Healthy Charities of Florida
Council for Affordable Health Coverage
CURE--The Bioscience Network of Connecticut
CVS Caremark

Decatur County Hospital
Deckerville Community Hospital
Delaware Academy of Medicine
Delaware BioScience Association
Delaware HIV Consortium
Delaware Public Health Association
Diabetes Community Action Coalition of Fulton County
Duval County Medical Society (DCMS)
East Cooper Community Outreach
Easter Seals
Easter Seals Arkansas
Easter Seals Iowa
Easter Seals Massachusetts
EDSers United
Elder Care Advocacy of Florida
Eli Lilly and Company
Embracing Latina Leadership AllianceS (ELLAS)
Epilepsy California
Epilepsy Foundation of East Tennessee
Epilepsy Foundation of Greater Los Angeles
Epilepsy Foundation of Northeastern New York
Epilepsy Foundation of San Diego County
Epilepsy Foundation of Western Wisconsin
Express Scripts
FAIR Foundation
Federation of Families for Children's Mental Health -Colorado Chapter
Filipino American Service Group Inc. (FASGI)
Florida HIV/AIDS Advocacy Network
Florida Partners in Crisis
Florida State Hispanic Chamber of Commerce
Generic Pharmaceutical Association
Georgia Bio
Georgia Osteoporosis Initiative
GlaxoSmithKline
GLMA: Health Professionals Advancing LGBT Equality
Global Genes Project
Global Healthy Living Foundation
Global Pharma Analytics, Inc.
H.E.A.L.S of the South
Hampton Roads Technology Council
HealthCare Institute of New Jersey (HINJ)
Healthcare Leadership Council
HealthHIV
Healthy Heritage Movement, Inc.
Heart Rhythm Society
Hep C Connection, Denver CO
Hepatitis Foundation International
HepFlorida
HepInfoNow
Hospira, Inc.
Human Rights Campaign

Humana
Illinois Biotechnology Industry Organization—iBIO®
Indiana Health Industry Forum
Indiana State Grange
Indianapolis Urban League
International Foundation for Autoimmune Arthritis
Iowa Biotech Association
Iowa Orthopaedic Society
Iowa State Grange
It's About Me Breast Cancer Awareness Association
Johnson & Johnson
Kentucky Chamber
Kentucky Life Sciences Council
Kidney Cancer Association
Latino Diabetes Association (LDA)
Let's Talk About Change
Licensed Professional Counselors Association of North Carolina
Life Sciences Greenhouse of Central PA
Lifelong AIDS Alliance
LifeScience Alley®
LPCA, the Licensed Professional Counselors Association of GA
Lupus Foundation of America
Lupus Foundation of America - DC/MD/VA Chapter
Lupus Foundation of America, Arkansas Chapter
Lupus Foundation of Florida, Inc.
Lupus Foundation of Mid and Northern New York, Inc.
Macular Degeneration Support
Massachusetts Association for Mental Health
Massachusetts Health Council
MassBio
Medical Alliance for MS (MA4MS)
Medical Oncology Association of Southern California, Inc
Medical Partnership for MS (MP4MS)
MedTech Association (NY)
Men's Health Network
Mental Health America of Colorado
Mental Health America of Georgia
Mental Health America of Indiana
Mental Health America of Texas
Mental Health Association in California
Mental Health Association in Tulsa
Mental Health Coalition of NC
Mental Health Systems
Merck
MichBio
Michigan Clinic
Michigan Lupus Foundation
Michigan Osteopathic Association
Michigan Rural Healthcare Preservation, Inc.
Minnesota State Grange
Missouri Association of Osteopathic Physicians and Surgeons

Missouri Biotechnology Association
MOBIO
Molly's Fund Fighting Lupus
Montana BioScience Alliance
Montana State Grange
Multiple Sclerosis Association of America
NAIFA - Alabama
NAIFA - Alaska
NAIFA - Arizona
NAIFA - Arkansas
NAIFA - California
NAIFA - Colorado
NAIFA - Connecticut
NAIFA - Delaware
NAIFA - Florida
NAIFA - Georgia
NAIFA - Greater Washington DC
NAIFA - Hawaii
NAIFA - Idaho
NAIFA - Illinois
NAIFA - Indiana
NAIFA - Iowa
NAIFA - Kansas
NAIFA - Kentucky
NAIFA - Louisiana
NAIFA - Maine
NAIFA - Maryland
NAIFA - Massachusetts
NAIFA - Michigan
NAIFA - Minnesota
NAIFA - Mississippi
NAIFA - Missouri
NAIFA - Montana
NAIFA - Nebraska
NAIFA - Nevada
NAIFA - New Hampshire
NAIFA - New Jersey
NAIFA - New Mexico
NAIFA - New York State
NAIFA - North Carolina
NAIFA - North Dakota
NAIFA - Ohio
NAIFA - Oklahoma
NAIFA - Oregon
NAIFA - Pennsylvania
NAIFA - Rhode Island
NAIFA - South Carolina
NAIFA - South Dakota
NAIFA - Tennessee
NAIFA - Texas
NAIFA - Utah

NAIFA - Vermont
NAIFA - Virginia
NAIFA - Washington
NAIFA - West Virginia
NAIFA - Wisconsin
NAIFA - Wyoming
NAMI Colorado
NAMI Florida
NAMI Georgia
NAMI Indiana
NAMI IOWA
NAMI Kentucky
NAMI Mass
NAMI Montana
NAMI Nebraska
NAMI North Dakota
NAMI Ohio
NAMI Oklahoma
NAMI South Carolina
NAMI Utah
NAMI-KC
National Alliance for Caregiving
National Alliance on Mental Illness
National Association of Health Underwriters (NAHU)
National Association of Hepatitis Task Forces
National Association of Hispanic Nurses - El Paso, Texas Chapter
National Association of Hispanic Nurses (NAHN)
National Association of Insurance and Financial Advisors (NAIFA)
National Association of Manufacturers
National Association of Nutrition and Aging Services Programs (NANASP)
National Association of Specialty Pharmacy (NASP)
National Coalition on Health Care
National Council for Community Behavioral Healthcare
National Council of Asian Pacific Islander Physicians
National Council of Negro Women Inc., View Park - Los Angeles
National Down Syndrome Society (NDSS)
National Gay and Lesbian Task Force
National Grange
National Hispanic Medical Association
National Medical Association
National Minority Quality Forum
National Osteoporosis Foundation
National Retail Federation
National Spasmodic Torticollis Association
National Tay-Sachs and Allied Diseases Association
NC Psychological Association & Foundation
NCBIO
Neurofibromatosis, Mid-Atlantic
New England Coalition for Cancer Survivorship
New Mexico Biotechnology & Biomedical Association (NMBio)
Newark Senior Center

NewYorkBIO
NJ Mayors Committee on Life Sciences
North Carolina AIDS Action Network
Novartis
Nuclea Biotechnologies, Inc.
Ohio Chamber of Commerce
Ohio State Grange
Older Americans of Florida
One in Four Chronic Health
OptumRx
Oregon Bioscience Association
Otsuka
Pacific Northwest Chapter of the Transplant Recipients International Organization (TRIO)
Parkinson's Association of San Diego
Partnership to Fight Chronic Disease (PFCD)
Pennsylvania Bio
Pfizer Inc
Pharmaceutical Care Management Association
Pharmaceutical Research and Manufacturers of America
Playing For Life
Plaza Community Services
Potomac Grange
Prescription Assistance Network of Stark County, Inc.
Prevent Cancer Foundation
Prime Therapeutics, LLC
Project ReDirect-DC
Psychiatric Society of Virginia
Puerto Rico AIFA
RAIN Oklahoma
Rare Disease United Foundation
Renal Support Network
RetireSafe
Rhode Island State Grange
Rio Grande Valley Diabetes Association
Rocky Mountain Stroke Center
Rush To Live
Salud USA
San Antonio AIDS Foundation
Sanofi
SCBIO
SD Biotech
Sickle Cell Disease Association of Florida
Skip To My Lupus, Inc
Small Business & Entrepreneurship Council
SoCalBio
Society for Women's Health Research (SWHR)
South Carolina Nurses Association (SCNA)
South Dakota CARES INC
South Dakota State Orthopaedic
Southern MS Consortium (seMSc)
StopAfib.org

Sunovion Pharmaceuticals Inc
Tech Council of Maryland
Tennessee Association of Health Underwriters
Tennessee Orthpaedic Society
Tennessee State Grange
Texas Association of Business (TAB)
Texas BioAlliance
Texas Conservative Coalition Research Institute
Texas Healthcare and Bioscience Institute
Texas Nurse Practitioners
Texas Renal Coalition (TRC)
Texas Transplantation Society
The AIDS Institute
The ALS Association
The ALS Association, Tennessee Chapter
The Arc of New Jersey
The G.R.E.E.N. Foundation
The Latino Coalition
The National Coalition for LGBT Health
Tuberous Sclerosis Alliance
U.S. Chamber of Commerce
United Spinal Association
United Way Association of South Carolina
US Pain Foundation
US Script
Virginia Bio
Wall-Las Memorias Project
Walmart
Washington Biotechnology & Biomedical Association (WBBA)
Washington Psychiatric Society
Washington State Nurses Association
WellPoint
Western Reserve Area Agency on Aging
Western Section of the American Urological Association
Women Against Prostate Cancer
Wound Care Clinic – ESU, Inc

Cc: The Honorable Dave Camp
The Honorable Orrin Hatch
The Honorable Sander Levin
The Honorable Fred Upton
The Honorable Henry Waxman
The Honorable Ron Wyden

Mr. PITTS. We have on our first panel today Mr. Jonathan Blum, Principal Deputy Administrator, Centers for Medicare & Medicaid Services, U.S. Department of Health & Human Services. Thank you for coming today. You will have 5 minutes to summarize your testimony. Your written testimony will be placed in the record. You are recognized for 5 minutes for your opening statement.

STATEMENT OF JONATHAN BLUM, PRINCIPAL DEPUTY ADMINISTRATOR, CENTER FOR MEDICARE, CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF HEALTH & HUMAN SERVICES

STATEMENT OF JONATHAN BLUM

Mr. BLUM. Thank you. Chairman Pitts, Ranking Member Pallone, members of the committee, thank you for the opportunity to discuss our thoughts on ways to improve the Part D Drug Program.

Mr. PITTS. Just pull that a little closer to you, if you can. Yes, thanks.

Mr. BLUM. We believe the Medicare Part D Program has never been stronger. All Medicare beneficiaries have many plan choices to select from, premium growth has been flat, and the Affordable Care Act took strong steps to close the Part D coverage gap or doughnut hole. By 2020, the gap will be completely closed.

In general, Medicare beneficiaries are satisfied with their drug coverage, and there is growing evidence that the Part D Drug Benefit has led to some decreases in other program costs.

While Medicare Part D is strong, we also see many vulnerabilities that can and should be addressed. This year, Medicare Part D will cost more than $70 billion, or about 12 percent of total program costs. According to CBO, total Part D spending is projected to grow dramatically faster than other parts of the program. These projected spending trends, as well as other vulnerabilities, led us to take a comprehensive review of the program, and to propose in an open and transparent way some changes to our current regulations. According to our actuaries, the proposed rule will reduce overall program costs and Part D premiums.

In addition to rapid spending growth, we see other vulnerabilities in Part D. First, while we see broad measures of beneficiary satisfaction, CMS receives far too many complaints from beneficiaries. In 2013, the program received over 30,000 complaints from beneficiaries regarding their Part D coverage. Far too high. Second, we see very high rates of inappropriate prescribing. While we are very, very sensitive to the concerns we have heard over changing the Protected Classes designation for three drug classes, we have to acknowledge the requirement for Part D plans to cover all drugs in these classes, with very little restriction, has led to harmful overprescribing—particularly antipsychotic drugs to sedate nursing home patients. Third, the program has too much prescriber fraud. This agency made a commitment to the Homeland Security Committee to reduce this fraud. This proposed rule honors that commitment. Fourth, we have seen too many Part D sponsors have significant compliance issues that have resulted in harm to

Medicare beneficiaries. Fifth, we see weak data evidence that preferred pharmacy networks always leads to cost savings for beneficiaries and the taxpayers. Sixth, while most beneficiaries have many plan choices, the evidence suggests that beneficiaries rarely change plans, even though they could reduce their out-of-pocket costs by changing plans. We support private plan competition in Medicare Part D, so long as beneficiaries can understand their choices and make changes easily. And seventh, CMS, under current regulations, cannot share detailed Part D claims data with outside researchers. We believe this data, if shared appropriately, can make the program even stronger.

Our proposed Part D rule is designed to address all these vulnerabilities, and to make the benefit work better for Medicare beneficiaries. In short, we believe that we must celebrate Part D's success, but also take a critical look at its vulnerabilities and take action where we can. The status quo is hardly perfect. However, we deeply respect the views of those who have stated their concerns and opposition to the rule, particularly patient groups and their concerns over the changes to the protected class definition. CMS will listen very carefully to the views of all Part D stakeholders and partners. We will make our final decisions after carefully reviewing all stakeholders' comments.

Thank you. Happy to address your questions.

[The prepared statement of Mr. Blum follows:]

STATEMENT OF
JONATHAN BLUM

PRINCIPAL DEPUTY ADMINISTRATOR AND DIRECTOR,
CENTER FOR MEDICARE
CENTERS FOR MEDICARE & MEDICAID SERVICES

ON

2015 CHANGES TO THE
MEDICARE ADVANTAGE AND THE MEDICARE
PRESCRIPTION DRUG BENEFIT PROGRAMS

BEFORE THE

U.S. HOUSE COMMITTEE ON ENERGY & COMMERCE,
SUBCOMMITTEE ON HEALTH

FEBRUARY 26, 2014

Statement of Jonathan Blum on
2015 Changes to the Medicare Advantage and the
Medicare Prescription Drug Benefit Programs
U.S. House Committee on Energy & Commerce, Subcommittee on Health
February 26, 2014

Chairman Pitts, Ranking Member Pallone, and members of the Subcommittee, thank you for inviting me to discuss the Centers for Medicare & Medicaid Services' (CMS) work to improve the Medicare Advantage (MA) Program and the Medicare Prescription Drug Program, also known as Medicare Part D, in Contract Year (CY) 2015. CMS is proud of our track record of successfully managing these important programs to ensure that beneficiaries have access to a wide range of high quality MA and Part D plans. We have proposed a number of improvements that will help protect taxpayer dollars and the integrity of the Medicare program while lowering costs, improving care quality, and enhancing protections for Medicare beneficiaries.

Medicare Advantage and Medicare Part D: A Track Record of Success

With Medicare Advantage enrollment at an all-time high and costs remaining stable, concerns that recent changes to the MA program would result in lower enrollment and higher costs now appear unfounded. Nationwide, over 15 million Medicare beneficiaries[1] are now enrolled in an MA plan. This is a 30 percent increase in enrollment since 2010, and enrollment is projected to continue increasing.[2] Plan participation continues to be robust with 99.1 percent of beneficiaries having access to an MA plan in their area. The average MA premium in 2014 is projected to increase by only $1.64 from last year, coming to $32.60.[3] At the same time, the average number of plan choices will remain about the same in 2014, and access to supplemental benefits remains stable.[4] Additionally, since passage of the Affordable Care Act, average MA premiums are down by 9.8 percent.[5]

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[1] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Monthly-Contract-and-Enrollment-Summary-Report-Items/Contract-Summary-2014-01.html?DLPage=1&DLSort=1&DLSortDir=descending
[2] 2013 Trustees Report pp. 166, 198. http://downloads.cms.gov/files/TR2013.pdf
[3] http://www.hhs.gov/news/press/2013pres/09/20130919b.html
[4] http://www.hhs.gov/news/press/2013pres/09/20130919b.html
[5] http://www.hhs.gov/news/press/2013pres/09/20130919b.html

Medicare Advantage plan quality continues to improve. Last year, CMS announced that over one-third of CY 2014 MA contracts will receive four or more stars, which is an increase from 28 percent in 2013.[6] In 2013, over half of MA enrollees were enrolled in plans with four or more stars, a significant increase from 37 percent of enrollees the previous year.[7] CMS calculates star ratings from 1 to 5 (with 5 being the best) based on quality and performance for MA and Medicare prescription drug plans to help beneficiaries, their families, and caregivers compare plans.

Like Medicare Advantage, the Medicare Part D prescription drug benefit program has been very successful. In its nine years of operation, Part D has made medicines more available and affordable for Medicare beneficiaries, leading to improvements in access to prescription drugs, better health outcomes, and greater beneficiary satisfaction with their Medicare coverage. In addition, the drug benefit is helping beneficiaries avoid the need for other services that would otherwise be covered under Medicare Parts A and B; the Congressional Budget Office (CBO) has estimated that a one percent increase in the number of prescriptions filled by beneficiaries causes Medicare's overall spending on medical services to fall by roughly one-fifth of one percent.[8]

The Medicare Part D program provides outpatient prescription drug benefits to about 38.5 million Medicare beneficiaries[9] through a wide range of plan choices, with plans competing to provide drug benefits to Medicare beneficiaries at an average monthly premium of about $30—a cost that has held steady for four years in a row despite the benefit becoming more generous.[10] According to surveys, 95 percent of Part D enrollees are satisfied with their drug coverage and confident that the level of coverage meets their needs.[11]

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[6] http://www.hhs.gov/news/press/2013pres/09/20130919b.html
[7] http://www.hhs.gov/news/press/2013pres/09/20130919b.html
[8] http://www.cbo.gov/sites/default/files/cbofiles/attachments/43741-MedicalOffsets-11-29-12.pdf.
[9] As of Jan. 2014. http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/index.html?redirect=/MCRAdvPartDEnrolData/
[10] http://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-Releases/2013-Press-Releases-Items/2013-07-30.html
[11] MedPAC. "Status Report on Part D." March 1, 2013. http://www.medpac.gov/chapters/Mar13_Ch15.pdf.

Meanwhile, the overall costs for the Part D program have risen more slowly than originally projected. According to CBO's data, Part D is on track to cost 45 percent less than projected for the initial 2004-to-2013 forecast period.[12] Additionally, the deductible and out-of-pocket limit in the standard Part D benefit will be lower this year than in 2013.

The quality of Part D plans is also improving. In 2013, the average star rating among standalone Part D plan sponsors, weighted by enrollment, was 3.3 stars out of five, compared with 2.96 stars for 2012.[13] These ratings are based on quality measures including patient safety and appropriate medication use metrics. Sponsors have incorporated the Medication Therapy Management Programs into their plans' benefit structures to ensure optimum therapeutic outcomes through improved medication use and a reduced risk of adverse outcomes.

In addition, the Part D program is even stronger since the enactment of the Affordable Care Act because beneficiary costs will be further reduced as coverage in the prescription drug coverage gap, or "donut hole," continues to expand. Since the Affordable Care Act was enacted, more than 7.3 million seniors and people with disabilities who reached the coverage gap in their Medicare Part D plans have saved $8.9 billion on their prescription drugs, an average of $1,209 per person since the program began.[14] This represents a dramatic reduction in the coverage gap, which will be closed by 2020.

Despite these achievements, in order for the Part D program to remain successful, we have to celebrate its successes and address its vulnerabilities. While beneficiaries are saving money, government subsidies for reinsurance and low-income cost sharing subsidies continue to increase. Moreover, Part D costs are projected to increase with the introduction of new, expensive biologic therapies, making it important for CMS to find ways to reduce costs when possible in order to keep premiums low. CMS is well aware of concerns related to fraud and abuse in the Part D program, as well as concerns that compliance with program requirements

[12] http://www.cbo.gov/sites/default/files/cbofiles/attachments/44205_Medicare_0.pdf
[13] MedPAC. "Status Report on Part D." March 1, 2013. http://www.medpac.gov/chapters/Mar13_Ch15.pdf
[14] http://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-Releases/2013-Press-Releases-Items/2013-11-26.html

could be improved. CMS appreciates the thoughtful work of the Congress[15] and the Department of Health & Human Services Office of the Inspector General[16] that highlights the potential for fraud, waste, and abuse in Part D. We are working to improve our efforts to reduce fraud and abuse in order to ensure that beneficiaries receive high-quality, appropriate care, while also making sure that we spend every Federal dollar as wisely as possible.

We also have to recognize that in some circumstances, due to current regulations, market-driven competition among Part D sponsors is not bringing down costs as efficiently as it could. For example, the current policy of requiring all Part D plans to include all drugs in the current six protected classes on their formularies significantly limits plan sponsors' ability to obtain price concessions for these drugs despite other redundant protections. This inhibits competition in the marketplace, unnecessarily increasing program costs for taxpayers and beneficiaries. Similarly, some plans with preferred pharmacy networks do not appear to result in savings—instead of passing along savings achieved through economies of scale, these Part D plans instead charge the Part D program higher prices, increasing taxpayer costs. Part D plans should earn a fair rate of return, but taxpayers and beneficiaries should benefit as well.

Key CY 2015 Improvements to the Medicare Advantage and Part D Programs

CMS strives to continually improve these programs to strengthen beneficiary protections, improve health care quality, and reduce costs. We do so by periodically revising the regulations governing the MA and Part D programs to implement statutory directives and to incorporate knowledge obtained through experience with each program. On January 6, 2014, CMS released a proposed rule with a comment period that includes provisions designed to reduce program costs, increase transparency, ensure consistent compliance with program rules by plan sponsors, and improve the quality of care for MA and Part D enrollees. The proposed rule also includes new Part D program integrity provisions that, if finalized, would give CMS new tools to help us combat fraud, waste, and abuse in Part D. These proposed regulations would implement MA and Part D technical and program changes, as well as provisions under the Affordable Care Act.

[15] For example, http://www.hsgac.senate.gov/subcommittees/Federal-financial-management/hearings/costs-of-prescription-drug-abuse-in-the-medicare-part-d-program

[16] HHS OIG has a large body of work examining Part D billing including: OEI-02-09-00603, OEI-02-09-00608, OEI-02-09-00140, OEI-03-11-00310, OEI-07-09-00150, OEI-07-10-06004

Most of the proposed provisions for the contract year 2015 result from insights obtained through practical experience with the programs—not only our experience but also that of stakeholders, whose questions and requests for further direction we address in many of the proposed regulations. This proposed rule is the latest of CMS' periodic revisions of MA and Part D regulations, and is a continuation of a multi-year strategy to simplify choices, make benefits more meaningful and transparent to beneficiaries, and lower overall costs.

Enhanced Strategy to Combat Medicare Part D Prescription Drug Fraud and Abuse

As the Part D program matures, CMS is broadening its initial focus of ensuring beneficiaries have access to prescribed drugs to also ensure that Part D includes effective safeguards to prevent fraud and drug abuse. CMS is aware of the growing problems of prescription drug abuse and inappropriate prescribing, and unfortunately, the Medicare Part D prescription drug program is not immune from the abuses associated with these nationwide epidemics. CMS takes these problems seriously. To combat prescription drug waste, fraud, and abuse more effectively, CMS evaluates Part D sponsors' operations to ensure that they are compliant with regulations, as well as the guidance in the Prescription Drug Benefit Manual. As part of program oversight, CMS uses the Fraud Prevention System (FPS) in Medicare fee-for-service to target investigative resources to suspicious claims and providers and swiftly impose administrative action when warranted.

Included in the proposed rule are a number of proposals that will, if finalized, provide the agency with new tools to employ when problematic prescribers and pharmacies are identified. One proposal would require prescribers of Part D drugs to enroll in Medicare in order for their prescriptions to be covered under Part D. Another provision would provide CMS the authority to revoke the Medicare enrollment of a prescriber for abusive patterns and practices of prescribing, or if the prescriber lacks a valid DEA Certificate of Registration. These two provisions, combined, will serve as an important safeguard that will help CMS ensure that Part D drugs are only prescribed by qualified individuals and provide CMS the authority to remove bad actors from the Medicare program, when appropriate, protecting beneficiaries and the Medicare Trust Fund from fraud, waste, and abuse.

New Criteria for Drug Classes of Clinical Concern

In the first year of the Medicare prescription drug benefit, CMS implemented a policy that required all Part D plans to include on their formularies "all or substantially all" Part D drugs within six drug classes—antineoplastics, anticonvulsants, antiretrovirals, antipsychotics, antidepressants, and immunosuppressants. CMS implemented the policy through subregulatory guidance in order to help smooth the transition of 6 million dual eligibles from Medicaid drug coverage to Part D in 2006. The Congress later directed CMS to identify categories and classes of Part D drugs for which all Part D drugs must be on the formulary using criteria established by CMS through notice and comment rulemaking.

Under the proposed rule, extensive beneficiary protections would continue and access to drugs in these classes would be ensured through adequate Part D formularies because CMS' formulary review is a clinically rigorous protection that ensures that each Part D formulary will meet the needs of most Medicare beneficiaries, and any beneficiary with atypical needs may submit a formulary exceptions request. Any beneficiary whose current medication is being removed from a formulary in the following coverage year will receive advance notice of this change, and that beneficiary will have an opportunity to choose a new plan during the annual election period that will cover that medication. However, it would be a mistake to assume that any current medications, especially brand-name medications, would no longer be broadly available on beneficiaries' current Part D plans as a result of our proposed policy change. This is not what we observe in drug classes today that are not subject to guaranteed formulary placement, and there is no reason to expect that manufacturer and purchaser behavior would be significantly different for historically "protected class" drugs. For example, when we look at 2014 formularies across drug classes that have as many products as are included in the antipsychotic and antidepressants classes, we see a 79 percent inclusion rate on average. Once the requirement to cover all drugs in a class was removed, we would expect manufacturers to negotiate for their products to remain on many formularies in order to retain as much market share as possible.

If, however, a beneficiary wishes to remain in a plan that will no longer cover a medication that he or she has been successfully stabilized on, that beneficiary will receive a transition supply and will have time to request a formulary exception. Under our transition requirements, the

beneficiary must receive at least 30 days of medication during the first 90 days of the plan year to allow for effectuation of the exception request or conversion to a formulary alternative. Fulfilling that exception request requires his or her prescriber to provide written or verbal attestation of why the formulary alternatives would jeopardize the patient's health, which under these circumstances should be supported by the patient's history. Importantly, the exceptions process is part of the upfront coverage determination process managed by the sponsors, and exception requests never need to progress into the appeals process as long as the prescriber provides the case-specific justification as to why the beneficiary cannot use a formulary alternative. Any time a beneficiary is going to leave a pharmacy without their prescription being filled, that beneficiary receives a printed notice of how to use these exception and appeals rights. Through complaint monitoring and both routine and risk-based audits, CMS has effective oversight of plans' compliance with the coverage determination/redetermination process. Where deficiencies are identified, we have been successful in bringing plans into compliance.

Under the proposed criteria for identifying categories and classes of drugs for which all Part D drugs much be on formulary, CMS would continue to require formulary inclusion of all drugs within the antineoplastic, anticonvulsant, and antiretroviral drug classes. However, CMS would no longer require all drugs from the antidepressant and immunosuppressant drug classes to be on all Part D formularies. The proposed change would not result in only two drugs on a formulary, but would result in at least the *minimum* required by our formulary inclusion reviews, which have been successful in ensuring access for other critical disease groups, including cardiac diseases, diabetes, lung diseases, and stroke. In the specific case of immunosuppressants, the proposed change in policy would not change our formulary requirements—we would require six drugs in this class, just as we do under current formulary review standards. CMS is also proposing to delay removing the protections from the antipsychotic class pending consideration of comments on whether there are any special transitional considerations that should be addressed prior to doing so. CMS recognizes that this would represent a change, and we will carefully review the comments before making any final decision.

Increased Competition

In light of our experience managing the Part D benefit and consistent with the Congress' directive to promote market competition in order to lower costs for the program and beneficiaries, CMS has proposed a number of interrelated regulatory provisions that are designed to improve price transparency and expand access to market-driven price competition. The proposed rule would require that all pharmacy price concessions are reflected in the drug prices paid by beneficiaries and the government, and it would ensure that any amounts rebated by pharmacies to Part D sponsors are used to lower the "negotiated price." The proposal would also put all Part D sponsors on a level playing field regarding how they report drug prices, improving the transparency of drug prices used on the Medicare plan finder and in the bids submitted by Part D sponsors.

To further improve market-driven price competition, the proposed rule would require that the lower copayments some Part D sponsors make available in a limited number of "preferred" network pharmacies steer beneficiaries toward lower priced drugs. While CMS agrees that preferred pharmacy networks can offer savings to Part D beneficiaries, we have found that a few sponsors have actually offered little or no savings on aggregate drug prices in their preferred pharmacy pricing, particularly in mail-order claims for generic drugs. Instead of passing through lower costs available through economies of scale or steeper discounts, some sponsors are actually charging the program higher negotiated prices and retaining any "savings" as higher profit. When these higher prices are combined with significantly lower cost sharing offered in preferred pharmacy pricing, such pricing increases the costs borne by the government. CMS supports maintaining or expanding access to preferred cost sharing levels, provided that there is better alignment between lower cost sharing levels for beneficiaries and lower negotiated prices for the program.

The proposed rule would also require Part D sponsors to allow any retail pharmacy willing to receive reimbursement at lower negotiated drug prices to contract with a Part D sponsor to have preferred cost sharing levels offered at the pharmacy. This proposal would allow more pharmacies—not just the pharmacies selected by Part D plans sponsor—to offer the most competitive drug prices, particularly for widely available low-cost generics, in order to be able to

attract customers with lower copayments offered under preferred cost sharing. As a result, the proposal, if finalized, should expand access for beneficiaries, particularly beneficiaries in rural areas, to more pharmacies that charge lower copayments for lower priced drugs. Expanding access to lower priced drugs also has the potential to reduce government expenditures on Part D. That said, we welcome comments on the implications of this policy.

More Meaningful Plan Choices

In order to ensure that beneficiaries have better ability to compare prescription drug plans with meaningfully different benefits and transparent costs, and because the Affordable Care Act's closing of the coverage gap has reduced the need for plans offering enhanced benefits, in the CY 2015 rule, CMS proposes that prescription drug plan (PDP) sponsors offer no more than two Part D plans in the same service area. On average, in 2014, every region has 17 basic plans and 17 enhanced standalone plans. Under the proposal, each organization would continue to be able to offer two plans in each area—one basic and one enhanced. CMS believes that the proposed policy would promote needed clarity of plan choices for beneficiaries without denying sponsors access to any truly innovative approaches they may take to designing plan benefit packages that meet Part D requirements.

To meet Part D requirements, all PDP sponsors must offer at least one basic plan per PDP Region, and all plans offered by the sponsor in a region must be meaningfully different from each other. Historically, sponsors, in addition to their basic plan offering, have used coverage for drugs in the coverage gap to distinguish their second and third plans. With the gradual reduction and closing of the coverage gap mandated by the Affordable Care Act that began in 2011, a feature of the Part D benefit that previously afforded sponsors greater opportunity to differentiate their own plans from each other and from the products of their competitors has largely been eliminated. As a result, sponsors' third plans represent little enhanced value over their second plans and have little appeal in the Part D market. Today, the enrollment in all "third" plans combined represents only two percent of the total enrollment in all stand-alone PDPs.

CMS believes beneficiaries will be better served by encouraging sponsors to focus on quality rather than quantity by developing innovative plan designs that have broad beneficiary appeal. In

addition, CMS believes this policy could help CMS use the bid review process to prevent plans from tailoring benefits in enhanced plans to attract healthier, lower-cost beneficiaries. This policy also could make it easier for beneficiaries to compare their options and select the Part D plans that best meet their needs. As with all proposals, we welcome comments on this policy.

Conclusion

CMS' role in managing the MA and Part D programs is to ensure strong choices and protect beneficiaries, while ensuring the fiscal integrity of the trust funds. To accomplish these goals, CMS has and will continue to take steps to make improvements. The proposed rule is a continuation of CMS' periodic strengthening of the regulations governing the MA and Part D programs and, as in the past, CMS will listen carefully to the comments from all stakeholders, reserving judgment until the comment period is closed and all stakeholders have had the chance to weigh in. CMS will continue to work with the Congress and this Committee in protecting taxpayer dollars, beneficiary health, and the integrity of the Medicare program.

Mr. PITTS. The Chair thanks the gentleman. And we will now go to questions and answers. I will begin the questioning. Recognize myself for 5 minutes for that purpose.

Mr. Blum, nonpartisan experts are warning us that millions of seniors will see higher costs and fewer choices if this regulation is finalized. Seniors in my district tell me how much they enjoy the Part D Program, many times when I talk to them.

As you acknowledge in your testimony, the Medicare Drug Benefit is under-budget, and 94 percent of seniors are happy with it. Why would CMS propose this regulation if everyone is telling us that it is going to force seniors to lose their plans, decrease access and increase cost?

Mr. BLUM. Well, a couple of points, Mr. Chairman. We see the overall Part D Program being a tremendous success, but the nonpartisan CBO projects that Part D spending in the next 10 years will grow faster than the other parts of the program. It is the fastest-growinig line item for the Medicare Program. The entire Medicare Program, since the Affordable Care Act, has dramatically been reduced, but for Part D. Part D is projected to be the fastest-growing program.

Now, CMS' proposed rule is a consistent path for us to simplify plan choices, to reduce, you know, kind of extra plans being offered by the same plan sponsors. CMS started this work back in 2010. We heard the same concerns from the plan industry, the PBM industry, that those changes would raise premiums, decrease choices, create greater dissatisfaction. That hasn't happened.

As you pointed out during your opening statement, the Part D premium has stayed flat, while at the same time we have reduced kind of extra plan choices dramatically, cut them in half. And looking at the past track record, the arguments that we are hearing today were similar arguments that we heard back in 2010, but those arguments back in 2010 did not prove true.

Mr. PITTS. Given the fact that the President's healthcare law cut $716 billion from seniors' Medicare Program, and we are already seeing how those cuts are negatively impacting seniors throughout the country, why should they believe that this proposed rule won't hurt them even more?

Mr. BLUM. Well, I think going back to the payment reductions that were passed in the Affordable Care Act, while we appreciate that there is now reduced spending within the Medicare Program, we see that every—signs on quality have increased. We see more private plans wanting to come into the program, we see premiums remain flat. The Part D premium this year was negative. Part D premiums, premiums for plans, have fallen, not risen. So we appreciate the fact that we are paying less today than we paid for some services before the Affordable Care Act, but every quality sign that we track, every quality sign that we measure, has gone up, premiums have gone down, and so we believe very strongly that beneficiary care, beneficiary costs have not been impacted by these changes.

Mr. PITTS. The law includes a noninterference clause, which prohibits the government from interfering with competition, and this has helped to prevent CMS from interfering with negotiations be-

tween drug plans and pharmacies. Such a prohibition has helped reduce costs for our seniors.

I and my colleagues read your regulation to violate the noninterference clause. In fact, department officials have weighed in against the very interpretation included in the proposed rule. I would ask that you open the document, document 1, in the document binder before you. This memo is from the HHS Inspector General, and I would ask you to read the highlighted portion of the document. You can go ahead and read that out loud.

[The information is available at http://docs.house.gov/meetings/IF/IF14/20140226/101788/HHRG-113-IF14-20140226-SD006.pdf.]

Mr. BLUM. So this is a statement to Kerry Weems back in 2008: "We agree that the Act prohibits the Government from interfering with negotiations between PDP sponsors and pharmacists and from instituting a price structure for the reimbursement of covered Part D drugs."

Mr. PITTS. Now, did you or agency staff specifically review the Inspector General's memorandum before issuing your proposed rule?

Mr. BLUM. I don't know. I can check. I personally did not, but I think it is important for us to explain why we chose to propose this change.

CMS, in the course of day-to-day interactions with plans and pharmacies and other entities, gets drawn into individual contract disputes. Plans ask us to arbitrate contract disputes with pharmacies and other entities. Pharmacies ask us to arbitrate disputes from Part D plans. And we agree, the statute is clear: CMS shall not interfere with the price structures. What we try to do is to articulate when and will not CMS interfere with these contract disputes.

Now, our challenge is on a day-to-day basis that plans and pharmacies ask us to arbitrate, and we wanted to propose a clear definition, not to degrade the noninterference clause but to strengthen it to make sure that we are absolutely clear with partners, stakeholders, when CMS won't arbitrate contract disputes, but we have no intention to negotiate price structures. The law is very clear. During my time on the Senate Finance Committee, that I had a hand in helping to draft that provision, I understand the intent, I understand why that was included.

Mr. PITTS. Well, you know, I am not sure it is responsible for agency staff to issue a rule that completely contradicts the written legal opinion of the HHS Inspector General.

So with that, I'll recognize the ranking member, Mr. Pallone, for 5 minutes for questions.

Mr. PALLONE. Thank you, Mr. Chairman.

You know, I know you mentioned, Mr. Chairman, the Medicare Advantage changes in the ACA, and as you know, nearly every Republican in the House of Representatives voted for or supported the very same changes or savings. In fact, the savings were part of the Republican budgets written by the House Budget Chair, Paul Ryan, in 2011, 2012, and 2013, and these same policies put in place by the ACA were continued in these budgets, and the majority of House Republicans voted for them in each of those years.

But let me ask Mr. Blum. If you listen to the critics of the proposed rule that you are discussing today, it sounds like the end of western civilization as we know it, and the refrain we keep hearing is that most beneficiaries are satisfied, and costs are lower than anticipated when the program was enacted 8 years ago, therefore, we should make no changes. And today's hearing is titled "Messing With Success." But, frankly, I believe that we should continually seek to improve Medicare for beneficiaries and taxpayers. It seems strange to me that people would want to block changes that could improve the program. In fact, organizations representing these so-called satisfied beneficiaries that we keep hearing about, such as the National Council on Aging, National Committee to Preserve Social Security, and Families USA, strongly support many of your proposed changes.

So could you comment on why CMS chose to move forward a proposal to further strengthen Part D at this time?

Mr. BLUM. Well, we see the program being tremendously successful. We also see that the program has many vulnerabilities. We receive recommendations from the IG frequently for us to take stronger steps to reduce prescriber fraud in the program. We see that, while the Part D premium has remained stable over the past several years, that is only one part of Part D's costs, and the Part D premium doesn't measure the complete cost of the program. Part D is projected to spend faster than other parts of the program, dramatically faster than the Part A Program, the Part B Program.

We feel it is our responsibility to propose changes to improve the operations. We also feel that it is our responsibility to do it through the propose and notice comment period. We want to create a conversation about the best ways to improve the Part D Program. We respect and we will carefully review the comments, concerns and the criticisms, but for us to argue that the Part D Program is perfect, the status quo is perfect, is contrary to what we see as our obligations to this committee, to the Congress, and to the beneficiaries that we serve.

Mr. PALLONE. Well, I certainly agree. We have also heard that the unfettered competition in the Part D Program is responsible for bringing costs down below initial projections, and that the CMS rule is messing, I think the word is, with competition, but could you comment on what had led to the lower costs in Part D? I know you have already, but maybe a little more.

Mr. BLUM. Well, two points I think that are important for us to state on the record. If you speak to our CMS actuaries and ask them what has accounted for the lower costs than projected back in 2003, I believe the number 1 answer would be the fact that we have much more generic prescribing happening in the Part D Program, and the fact that we have fewer brand-new breakthrough medications right now on the market than the CMS actuary, and CBO, staff projected back in 2003. So it is not necessarily private competition that has caused the lower Part D cost trends previously, but the fact that we have kind of fewer brand-name drugs coming onto the program.

I think it is also important for this committee to understand that the Part D Program is not a truly competitive model, that it is not simply that CMS pays a fixed capitated payment to Part D plans;

they can negotiate said benefits as best they see fit. Medicare in many respects is a cost-based program. For the low-income beneficiaries, Medicare pays just about the full cost of the benefit, not based upon a fee schedule, but based upon the prices Part D plans negotiate. For beneficiaries that exceed certain thresholds, the catastrophic limit, Medicare pays just about the full cost of those drugs past that limit. So to say that Part D is competitive in a pure sense doesn't meet the statutory definition of the program, and I think what our actuaries tell us is that the primary reason that Part D spending has been lower than projected is the fact that we have more generic prescribing, due to the fact that we have fewer new brand-name drugs brought to market.

Mr. PALLONE. Thank you. Mr. Chairman, I have 4 letters—I would ask unanimous consent. I have 4 letters in support of the rule and the provisions that foster greater transparency and competition, as well as enhance beneficiary protections, from beneficiary advocacy groups, including the Medicare Rights Center, Families USA, Independent Specialty Pharmacy Coalition, and the National Community Pharmacists Association.

Mr. PITTS. Without objection, so ordered.

[The information follows:]

February 25, 2014

U.S. House of Representatives
Committee on Energy & Commerce
Subcommittee on Health
Washington, DC 20515

Re: Subcommittee Hearing "Messing with Success: How CMS' Attack on the Part D Program Will Increase Costs and Reduce Choices for Seniors" (February 26, 2014)

Dear Chairman Pitts and Ranking Member Pallone:

The undersigned organizations share a commitment to advancing the economic and health security of older adults, people with disabilities and their families. We strongly encourage members of this Committee to analyze each part of the proposed rule regarding Medicare Advantage (MA) and Part D plans that is the subject of this hearing—as opposed to endorsing or rejecting the proposed rule in its entirety.[1]

The proposed rule contains significant improvements in consumer protections and plan oversight. While we are concerned about some individual provisions, such as the proposed change in Part D protected drug classes, we are strongly supportive of increased oversight of MA and Part D plans as well as expanded access to affordable pharmacies and cost-sharing for Medicare beneficiaries. We urge that the proposed provisions we support be made final.

The Proposed Rule Would Enhance Informed Beneficiary Decision-Making, Improve Access to Affordable Drugs, and Strengthen Plan Oversight.

We strongly support a number of provisions in the proposed rule, including:

Plan consolidation – CMS proposes to limit the number of Part D plans that can be offered by a plan sponsor to one basic and one enhanced plan per region. We strongly support this effort to improve consumers' decision-making by encouraging more meaningful differences among plans. An abundance of similar plan choices has often led to inertia among overwhelmed beneficiaries as few enrollees change plans, even though many could save money and have improved access to needed drugs if they enrolled in a plan better suited their individual needs. We agree with CMS that the proposed plan consolidation will help prevent anti-competitive "gaming." As noted by CMS, a more streamlined bid submission process will better serve beneficiaries, taxpayers, and plan sponsors themselves.

Drug price fairness, accuracy and affordability – A number of proposals combined will save both plan enrollees and the Medicare program money by more fairly calculating and reporting drug prices and will increase access to preferred pharmacies. First, the proposed standardization of reporting *negotiated drug prices* will ensure that reported prices accurately reflect the agreed-upon prices between network pharmacies and a PDP. This is necessary to ensure that PDPs cannot game the system and obtain higher Medicare reimbursements by failing to report network pharmacy concessions in the negotiated price. This proposal would both save Medicare dollars and improve beneficiaries' ability to accurately gauge plan costs via the online Medicare Plan Finder. Second, CMS plans to codify requirements that preferred pharmacies, through *preferred cost-sharing*, actually save

[1] 79 Federal Register 1918 (January 10, 2014).

money for Medicare. Among other things, this would prevent plans from creating cost-sharing structures that drive consumers to mail order pharmacies costing Medicare more than non-preferred retail pharmacies. Third, proposed changes applying the *any willing pharmacy* standard to preferred networks will increase beneficiary access and reduce beneficiary costs. We also strongly endorse the requirement that pharmacies in a preferred network must consistently charge preferred cost sharing and consistently bill no more than the ceiling price for all prescriptions. Beneficiaries have the right to a system that is predictable and understandable.

Strengthened plan oversight – CMS proposes a number of measures to improve oversight of Medicare's contracts with MA and Part D plans sponsors, including: requiring a minimum level of experience; increasing audit capacity; enhancing contract termination authority; and enforcing quantifiable plan quality improvement through the star rating metrics. These measures will help enforce consumer protections and enhance adequate stewardship of Medicare funds paid to private plans.

Other important consumer protections in the proposed rule include: increasing access to medication therapy management (MTM) through an expansion of eligibility criteria; improved beneficiary notices; and requirements that MA plans with prescription drug coverage take steps to appropriately deal with Part D denials of coverage for drugs that should be covered under Parts A or B. All combined, these proposals will significantly improve the functioning and efficiency of both the MA and Part D programs.

The Proposed Changes in Protected Drug Classes Will Limit Beneficiary Access to Essential Medicines.

While we support the provisions of the proposed rule that improve access to care and enhance oversight and accountability of plans, we are concerned with some of the provisions, in particular, the proposal to alter how the clinical classes of concern criteria for Part D drugs ("protected classes") are defined. CMS proposes replacing current rules requiring Part D plans to cover substantially all available drugs in six designated protected classes with a two-step test to determine which categories of drugs are of sufficient clinical concern to merit continued protected status. Upon application of this test to the current protected classes of drugs, CMS concludes that antidepressants, immunosuppressants, and antipsychotics no longer meet the requirement for protected drug class status. If implemented, disruption to beneficiaries' current medication therapy will cause considerable challenges for individuals with serious health conditions. We take issue with the requirements in the two-step test, in part, because the test would set too high a bar for when drug classes would receive protected status. In addition, we dispute CMS' underlying assumptions about the efficacy of existing consumer protections in ensuring adequate access to needed medications. Without disposing of the rest of the proposed rule, we urge that this proposal be rejected and that the current protected class criteria remain in effect.

Program Improvements Needed Beyond Those in Proposed Rule.

While it is clear that the Part D program has provided prescription drug coverage to many Medicare beneficiaries who previously did not have access to such coverage, there is still much room to improve the Part D program. Instead of the efficiencies of the private market bringing costs below initial estimates, Part D cost savings are largely attributable to lower than expected enrollment and decreased per-capita prescription spending nationwide due to increased generic drug use, major drugs coming off patent, and fewer blockbuster drugs coming to market.

There are number of steps that should be taken to make the Part D program work better for the Medicare beneficiaries it serves, including improving the appeals system and notices, altering the specialty-tier framework, and further enhancing informed consumer decision-making. We welcome the opportunity to work with your Committee to achieve these goals.

Thank you for the opportunity to submit these comments for the record.

Sincerely,

Alliance for Retired Americans
American Federation of State, County and Municipal Employees (AFSCME)
California Health Advocates
Center for Medicare Advocacy, Inc.
Medicare Rights Center
National Committee to Preserve Social Security and Medicare
National Council on Aging
National Senior Citizens Law Center

FamiliesUSA
The Voice for Health Care Consumers

House Committee on Energy and Commerce
Subcommittee on Health

Messing with Success: How CMS' Attack on the Part D Program Will Increase Costs and Reduce Choices for Seniors

Written Statement for the Record
Families USA
Ron Pollack, Executive Director

February 26, 2014

Dear Chairman Pitts and Ranking Member Pallone,

On behalf of Families USA, thank you for the opportunity to submit this written statement for the record for the hearing entitled, *"Messing with Success: How CMS' Attack on the Part D Program Will Increase Costs and Reduce Choices for Seniors."*

We are concerned that, judging from the title of this hearing, the Committee has already determined that the proposed CMS rule will be detrimental to beneficiaries. We strongly disagree with this assessment. As discussed below, several elements in the proposed rule would improve Medicare Part D for beneficiaries and taxpayers. We believe that the Committee should ground its oversight of the Parts C and D programs in ensuring what's best for beneficiaries and the American taxpayer, and not in protecting particular industries.

Plan Consolidation

We support CMS's proposal to limit parent organizations to one sponsor contract per PDP region and to limit the number of prescription drug plans (PDPs) that can be offered by a plan sponsor to one basic and one enhanced plan per region. Limiting the number of plans to those with meaningful difference will make it easier for beneficiaries to make an informed choice. Evidence suggests that today beneficiaries are so overwhelmed by the number of plans that they often stay in their current plan, even though switching plans could save money both for themselves and Medicare. We also strongly support CMS's desire to prevent anti-competitive practices by which insurers segregate high-cost, low-income beneficiaries into particular plans. CMS also deserves commendation for seeking to limit the number of sponsor contracts, which will improve the reliability of the quality star rating system, thereby enhancing plan accountability.

Changes to Drug Pricing Rules

Reporting Negotiated Drug Prices: The proposed standardization of reporting negotiated drug prices will ensure that reported prices accurately reflect the agreed-upon prices between network pharmacies

and a PDP. Today, PDPs can obtain higher Medicare reimbursements by failing to report network pharmacy concessions in their negotiated price. The proposed change would both save Medicare dollars and improve beneficiaries' ability to accurately gauge plan costs via the online Medicare Plan Finder.

Preferred cost-sharing: We support CMS's proposal to codify requirements that preferred pharmacies, through preferred cost-sharing, actually save money for Medicare. Among other things, this would prevent plans from creating cost-sharing structures that drive consumers to mail order pharmacies costing Medicare more than non-preferred retail pharmacies.

Pharmacy rules: We believe the proposal to allow any willing pharmacy to participate in lower cost-sharing will benefit consumers by increasing beneficiary access to pharmacies and reducing beneficiary costs. We also strongly endorse the requirement that pharmacies in a preferred network must consistently charge preferred cost sharing and consistently bill no more than the ceiling price for all prescriptions. Beneficiaries have the right to a system that is predictable and understandable.

Strengthened plan oversight

CMS proposes a number of measures to improve oversight of Medicare's contracts with Medicare Advantage and Part D plan sponsors, including: requiring a minimum level of experience; increasing audit capacity; enhancing contract termination authority; and enforcing quantifiable plan quality improvement through the star rating metrics. These measures will help enforce consumer protections and enhance plan accountability.

Protected Classes of Drugs

We have concerns that the proposed changes to the rules governing protected classes of drugs need further refinement. In particular, CMS may be overly optimistic about the viability of the appeals system and current transition rules as a way to ensure beneficiaries' access to appropriate drugs. Health care providers need a great deal of education and support to learn how to assist beneficiaries navigating these systems before the systems can be relied on as a back-up means of ensuring access.

In summary, while there are elements in the CMS proposed rule that merit close consideration, many of the changes would benefit Medicare beneficiaries and taxpayers. We urge the committee to approach the proposed rule thoughtfully.

Thank you for the opportunity to submit this statement into the hearing record.

Sincerely,

Ronald F. Pollack
Executive Director

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February 25, 2014

The Honorable Joe Pitts, Chairman
Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
420 Cannon House Office Building
Washington, D.C. 20515

The Honorable Frank Pallone, Jr.,
Ranking Member
Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
237 Cannon House Office Building
Washington, D.C. 20515

Re: Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs

Dear Chairman Pitts and Ranking Member Pallone,

On behalf of the Independent Specialty Pharmacy Coalition ("ISPC") we are pleased to submit the following statement concerning the "Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs" ("proposed rule") recently proposed by the Centers for Medicare & Medicaid Services ("CMS"). The ISPC commends CMS for taking a stand against over restrictive prescription drug plan networks, improving transparency, and ensuring lower costs and higher quality of care for Medicare beneficiaries. We ask this letter be submitted into the record for the February 26, 2014 hearing on the proposed rule by the Subcommittee on Health to the U.S. Representatives Committee on Energy and Commerce.

The ISPC is a coalition made up of a number of leading specialty pharmacy across the country formed in 2010 with the intent of providing independent specialty pharmacies with a voice in regulatory and legislative matters. We serve thousands of specialty patients who value the service, counseling and assistance they receive from community specialty pharmacies.

The Nature of Specialty Pharmacy

Specialty pharmacies provide treatments for our nation's most vulnerable patient populations suffering from chronic, complex conditions such as hemophilia, Crohn's Disease, hepatitis C, infertility, HIV/AIDS, and many forms of cancer. The specialty treatment for these conditions are generally very expensive, and often require special handling and control as well as complex

administration, as is the case with injectables and infusions. Given the dynamic nature of many of these disease states, intensive and consistent monitoring is vital to effective patient care in this area.

Independent specialty pharmacies provide a vital level of clinical pharmacy services to the hundreds of thousands of Medicare beneficiaries that depend on specialty treatments. We are not mere drug dispensaries, but instead play an active role in providing continuity of patient care to ensure that costs are minimized and health outcomes improve. We work with clinicians to set up treatment regimens, coordinate care, and determine the effectiveness of treatments. We educate patients on effective utilization, how to inject and administer medications, and how to detect adverse side effects. In many situations, specialty pharmacies serve as the critical link between doctors and patients in monitoring therapy, including side effects, medication combinations, and ineffective treatments. The services provided by specialty pharmacies support the most cost-effective use of these expensive treatments and help to keep these patients healthy and out of hospitals. Independent specialty pharmacies are hugely valuable, therefore, for protecting these beneficiaries' wellbeing and containing health care costs to the Medicare program.

Restricted Pharmacy Networks

As representatives of independent specialty pharmacies, we have long supported increased access for beneficiaries. When Congress enacted Medicare Part D, the goal was to preserve patient access and choice by permitting any willing pharmacy to participate in a prescription drug plan ("PDP") network so long as it met the plan's conditions. Unfortunately, restricted Part D networks have become common place, particularly those run by pharmacy benefit managers that own their mail order pharmacy, severely limiting the choice beneficiaries have in access to pharmacies. Restricted networks are even more problematic as specialty drug spending is increasingly expensive and is quickly becoming the leading drug spend for Medicare prescription drug plans, vastly outpacing spending on other brands and generics.

Restricted networks can harm consumers. These restrictive networks deprive beneficiaries of crucial services. Beneficiaries are often forced to abandon relationships with their preferred pharmacy, for a preselected retail or mail order pharmacy, which often lacks the specialty services provided by independent specialty pharmacies.

CMS recognizes in its proposed rule that the utilization of preferred networks should reflect a lower total cost for prescription drugs. However this is not what is has found. Rather CMS states that few PDPs "have actually offered little or no savings in aggregate in their preferred pharmacy pricing, particularly in mail-order claims for generic drugs." Therefore, CMS now proposes to eliminate these restrictive networks in favor of preferred cost sharing open to any willing pharmacy.

For these reasons, we fully support CMS's proposals to allow any willing pharmacy to participate in new preferred cost sharing networks. [1] If applied, these new networks will ensure increased pharmacy participation and therefore greater patient access while not increasing costs for plans, Medicare, or beneficiaries.

[1] We offer no opinion at the moment on other provisions offered by CMS in the proposed rule.

Please contact us for any questions or further information.

Sincerely,

David A. Balto

David A. Balto

February 25, 2014

The Honorable Marilyn B. Tavenner, Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-4159-P
P.O. Box 8013
Baltimore, MD 21244-8013

Dear Administrator Tavenner:

We want to take this opportunity to voice our strong support for certain proposed changes to the Medicare Part D prescription drug program that will allow more meaningful beneficiary choice and increased marketplace competition. The undersigned organizations represent key healthcare providers who have been on the front lines of providing medications and related counseling to Medicare beneficiaries since the inception of the Part D program as well as drug supply chain participants.

We stand in strong support of the following provisions contained in the proposed rule:

- ***CMS' Interpretation of the Non-Interference Provision and Timely Updates to Drug Pricing Standards:*** We agree the *Medicare Modernization Act* non-interference provision was intended to address negotiations related to the selection of drug products that would be covered under Part D formularies, and was not meant to prohibit CMS guidance that ensures the Part D marketplace operates in a fair and efficient fashion. We commend CMS for recognizing additions to what constitutes a "prescription drug pricing standard." We support CMS' expectations that pharmacies should have current data on the amount of reimbursement they can expect, which in turn impacts costs that plan sponsors submit to CMS as well as prices displayed on Plan Finder.
- ***Preferred Cost Sharing for Beneficiaries and Any Willing Pharmacy Standard Terms & Conditions:*** We applaud CMS for formally recognizing that, although the agency was led to believe that its costs via preferred pharmacy networks to be uniformly lower, CMS' own findings proved otherwise. We support CMS' proposal to require Part D plan sponsors to offer terms & conditions for every level of cost sharing, including preferred cost sharing, to any willing pharmacy that will accept the terms. This proposal will benefit seniors by giving them more choice among pharmacies in their drug plan, and will lead to increased competition in the marketplace.
- ***Expansion of Medication Therapy Management Program (MTM) Under Part D:*** MTM services are critical to patient understanding and adherence to their medication regimens, and are ideally provided face-to-face by a pharmacist. We fully support the agency's efforts to expand access to these critical services and agree with CMS that MTM must become a cornerstone of the Prescription Drug Benefit, and that studies have shown the positive impact on patient outcomes and costs that MTM provides.

We ask that CMS finalize these provisions, without changes, in an expeditious manner in order to bring meaningful choice and competition to the Part D Program.

Sincerely,

Alaska Pharmacists Association
Alliance of Independent Pharmacists of Texas
American Association of Colleges of Pharmacy
American Pharmacies
American Pharmacy Cooperative, Inc.
American Pharmacy Services Corp.
AmeriClear Rx
Appro-Rx
Arizona Pharmacy Association
Arkansas Pharmacists Association
Associated Fresh Markets
Association of Community Pharmacists Congressional Network
Astrup Drug, Inc.
Aurora Pharmacies
Bartell Drugs
Big Y Foods, Inc.
Brookshire Grocery Company
California Pharmacists Association
CARE Pharmacies Cooperative, Inc.
Cecil 's Pharmacy
Chain Drug Marketing Association
Community Pharmacy Prescription Network
Compliant Pharmacy Alliance Cooperative
Connecticut Pharmacists Association
Dan's Fresh Market
Davis Food and Drug
DiCello & Associates, Inc.
Dick's Fresh Market
Digital Simplistics, Inc.
Discount Drug Mart, Inc.
Drug Emporium Pharmacies
EPIC Pharmacies, Inc.
EPIC Pharmacy Network, Inc.
Fagen Pharmacy
FDS, Inc.
Federation of Pharmacy Networks
Florida Pharmacy Association
Frank W. Kerr Co.
Fresh Encounter, Inc.
Fruth Pharmacy
Garden State Pharmacy Owners, Inc.

Georgia Pharmacy Association
GeriMed
GPhA Academy of Independent Pharmacy
Guardian Pharmacy
Harmon's
Hartig Drug
Hi-School Pharmacy Inc.
HomeTown Pharmacy Inc.
Hy-Vee Pharmacies
Idaho State Pharmacy Association
Illinois Pharmacists Association
Independent Pharmacy Alliance
Independent Pharmacy Buying Group, Inc.
Independent Pharmacy Cooperative
Innovatix, LLC
International Academy of Compounding Pharmacists
Iowa Pharmacy Association
Kansas Independent Pharmacy Service Corp.
Kansas Pharmacists Association
Kelley-Ross Long Term Care Pharmacy
Kentucky Pharmacists Association
Keystone Pharmacy Purchasing Alliance
King Kullen Pharmacies
Kinney Drugs, Inc.
Kopp Drug
La Farmacia de la Gente
Lagniappe Pharmacy Services
Lifecheck Pharmacies
Lin's Fresh Market
Long Island Pharmacists Society
Louisiana Independent Pharmacies Association
Macey's Supermarkets
Mallatt's Homecare Pharmacy
Managed Health Care Associates, Inc.
Maryland Pharmacists Association
Massachusetts Independent Pharmacists Association
Massachusetts Pharmacists Association
MedOne Healthcare Systems
Merwin LTC Pharmacies
Michigan Pharmacists Association
Minnesota Pharmacists Association
Mississippi Independent Pharmacies Association
Missouri Pharmacy Association
Montana Pharmacy Association
Mutual Wholesale Drug Company
National Alliance of State Pharmacy Associations

National Community Pharmacists Association
National Grocers Association
National Rural Health Association
Navarro Discount Pharmacies, LLC.
Nebraska Pharmacists Association
New Jersey Pharmacists Association
New Mexico Pharmacists Association
Niemann Foods, Inc.
North Dakota Pharmacists Association
Northeast Pharmacy Service Corporation
Northwest Specialty Pharmacy
NoviXus Mail Service Pharmacy
Ohio Pharmacists Association
Osborn Drugs, Inc.
Our Valley Pharmacy
Pace Alliance
Pakistani American Pharmaceutical Association
Partners in Pharmacy Cooperative
PBA Health/TrueCare Pharmacies
PCCA
Pennsylvania Pharmacists Association
PerroneRX, LLC
Pharmacists Society of the State of New York
Pharmacists United for Truth and Transparency
Pharmacy Plus Network
Pharmacy Provider Service Corp.
Pharmacy Society of Wisconsin
Philadelphia Association of Retail Druggists
PPOk RxSelect Pharmacy Network
PPSC
Progressive Pharmacies
QS/1 Data Systems
Quality Care Pharmacies
QuickChek Pharmacies
Raley's Family of Fine Stores
Ralph's Thriftway Pharmacy
Red Cross Pharmacy
Ritzman Pharmacies
Rochester Drug Cooperative, Inc.
RxPlus Pharmacies
RxPreferred Benefits
Sav-Mor Drug Stores
Sav-On Drugs
ShopRite
Smith Drug Company
South Carolina Pharmacy Association

Southern Pharmacy Cooperative
Tennessee Pharmacists Association
Texas Independent Pharmacies Association
Texas Pharmacy Association
Texas Pharmacy Business Council
Third Party Station
Thrifty White Pharmacy
Town & Country Markets
United Drugs
Value Drug Company
Value Merchandiser Company
Virginia Pharmacists Association
Walker Drug
Washington State Pharmacy Association
Weis Markets
West Virginia Pharmacists Association
Woods Supermarkets
Wray's Marketfresh IGA

Cc: The Honorable Kathleen Sebelius

Mr. PALLONE. Thank you.

Mr. PITTS. The Chair thanks the gentleman. Now recognizes the vice chair of the full committee, Mrs. Blackburn, 5 minutes for questions.

Mrs. BLACKBURN. Thank you, Mr. Chairman. Thanks, Mr. Blum, for being here.

Avalere has said that the changes you are going to make would eliminate 39 percent of all of the enhanced plans by 2016, and that would be 214 of the current 552 enhanced PDP's to be terminated or consolidated.

So what would you say to the seniors in my district who like the plan that they have but cannot keep it if you get your way?

Mr. BLUM. Well, there are a couple of things, Congresswoman. First is that CMS, since 2009, has put in place a strategy to reduce the number of kind of extra plans that sponsors provide. We started that process back in 2009/2010. We heard the same——

Mrs. BLACKBURN. You are doing this through the rules?

Mr. BLUM. Correct.

Mrs. BLACKBURN. OK. Let me ask you this. Avalere also said that the regulation would impact 7.4 million of the 7.9 million Medicare beneficiaries who are enrolled. That is 94 percent. So why would you and the President support a regulation which is going to disrupt 94 percent of seniors in Medicare Part D who have a plan that they like, and would really like to keep it but you are not going to let them do that?

Mr. BLUM. So I think it is important to think about the history of the marketplace. Before the doughnut hole was closed, Part D plans oftentimes offered kind of supplemental benefits to fill in that doughnut hole. The doughnut hole is now being closed due to the Affordable Care Act.

By 2020, the doughnut hole will be completely closed. There have been very strong steps so far to close that doughnut hole. We see——

Mrs. BLACKBURN. OK——

Mr. BLUM [continuing]. Little opportunity for Part D plans really to distinguish themselves from other plans——

Mrs. BLACKBURN. So you see this——

Mr. BLUM [continuing]. Those same sponsors offered——

Mrs. BLACKBURN [continuing]. As an opportunity?

Mr. BLUM. We see this as a way to simplify the Part D Program, to make it much easier to navigate. The concerns that——

Mrs. BLACKBURN. So by limiting choice and options, you see that as a simplification and a way to improve this program?

Mr. BLUM. I think some of the concerns that I hear, oftentimes from the beneficiary community, are that there are many Part D choices, too many to choose from, and we know from academic literature that the more choice, more confusion——

Mrs. BLACKBURN. So you think people are confused?

Mr. BLUM. I think——

Mrs. BLACKBURN. That seniors are confused——

Mr. BLUM. I personally hear——

Mrs. BLACKBURN [continuing]. And they need CMS to——

Mr. BLUM. I personally hear——

Mrs. BLACKBURN [continuing]. Simplify that?

Mr. BLUM [continuing]. Tremendous confusion——

Mrs. BLACKBURN. OK, let me——

Mr. BLUM [continuing]. From the beneficiary community.

Mrs. BLACKBURN. Let me ask you another question. You have talked about actuaries a lot. Are you listening to actuaries or enrollees?

Mr. BLUM. We listen to both beneficiaries——

Mrs. BLACKBURN. You are listening to both?

Mr. BLUM [continuing]. And——

Mrs. BLACKBURN. OK.

Mr. BLUM. And to our career actuaries.

Mrs. BLACKBURN. OK. Well, you know, the surveys show that 95 percent of the seniors are satisfied with their plan, and Part D is estimated to cost 48 percent less than initially estimated by the CBO, and Milliman has projected that if your new rule goes into effect, the Federal Government will be on the hook for $1.6 billion more than expected in 2015. So where are you going to get the money?

Mr. BLUM. So I think a couple of things. I think we see a future for the Part D Program that is growing very quickly; 10 percent per year. That is dramatically faster than other parts of the program.

Mrs. BLACKBURN. OK.

Mr. BLUM. So to say that we shouldn't take a critical look at the future, we don't agree.

We heard the same concerns back in 2010 that premiums would skyrocket, beneficiaries would be left by their plan when CMS started to——

Mrs. BLACKBURN. Yes, we heard that——

Mr. BLUM [continuing]. Consolidate—.

Mrs. BLACKBURN [continuing]. About the Affordable Care Act, and that indeed is happening. I will tell you, I have plenty of stories I can share with you there.

Well, if Part D is not broken, then why do you think you need to go put something in here that is going to cost more, limit options, take seniors out of their plans, you know, it doesn't make a whole lot of commonsense, Mr. Blum. And I think that what we would like to do is see seniors who have a product they like, they are satisfied, bear in mind Medicare is something seniors have had money coming out of their paycheck every day of their working life and going into a Medicare trust fund, and they have prepaid their participation in this program, and I think that CMS needs to be listening to those enrollees and maybe paying less attention to these actuaries that obviously are going to give you—let me ask you this. What is your goal? What are you trying to achieve by this? What is your outcome?

Mr. BLUM. I think we have several goals. We want to reduce the prescriber fraud in the program, we want to make the benefit less confusing, more clear to our beneficiaries, we want to make sure that when the program pays the majority of costs for low-income beneficiaries, that we are paying the best possible rates. When we see preferred pharmacy networks being created, we want to encourage innovation——

Mrs. BLACKBURN. OK.

Mr. BLUM [continuing]. So long as those cost savings get passed on to our beneficiaries, passed on to the taxpayers.

Mrs. BLACKBURN. OK.

Mr. BLUM. So Part D, yes, has been tremendously successful, but we do not think it is perfect, nor do we get that——

Mrs. BLACKBURN. My time has expired. One last question. Can you cite for me the statute that gives you the opportunity to go in and settle these disputes between the manufacturers and the pharmacies?

Yield back.

Mr. BLUM. Sorry, is that a question or——

Mr. PITTS. Did you want to respond?

Mr. BLUM. We are happy to provide our legal clarification. We see that the changes to the noninterference don't weaken, but they strengthen. On a day-to-day basis we are pulled into many disputes that we feel that we need to provide clear rules.

Mr. PITTS. OK. The Chair thanks the gentlelady and now recognizes the ranking member of the full committee, Mr. Waxman, 5 minutes for questions.

Mr. WAXMAN. Thank you, Mr. Chairman.

Mr. Blum, there is a lot of concern about the proposed rule removing two classes of drugs, antidepressant and immunosuppressants, from the list of protected classes. I would like to hear your rationale. I know there are cost concerns, and cost concerns are always legitimate.

When I did my oversight work on Part D in 2007 and 2008, my investigations also revealed the prices for the drugs on the Protected Classes list were much higher than they should have been, but I think seriously the concerns that have been expressed by patients, that removing drugs from the Protected Classes list will mean their Part D plans may not cover them, and seniors will not be able to get the drugs they need.

Give us your rationale here.

Mr. BLUM. Well, I think we came to this proposal with difficulty, with much analysis, and kind of weighing the pros and cons for a proposed change, and one of the reasons why we felt comfortable to take a careful step towards lifting the class definition is that the Part D Program has many protections built into place; the appeal system, transition policy, the very rigorous formulary review that we do for Part D plans.

We cover drugs in about 140 drug classes, and we have 6 classes that are now protected, and other drug classes that treat very important conditions, diabetes, hypertension, congestive heart failure, don't receive this designation, yet we don't hear the concerns regarding beneficiaries having access to the drugs they need.

Mr. WAXMAN. Well, there are a lot of concerns being expressed——

Mr. BLUM. Sure.

Mr. WAXMAN [continuing]. About this, and I appreciate your efforts to reduce the taxpayer cost, and I know you are serious about making sure that seniors can get the drugs they need, but I believe there is a better way, and I have introduced to the last two Congresses the Medicare Drug Savings Act that would end one of the worst giveaways that was included in the original Part D bill.

For people who were covered by Medicaid, before Part D, there was a rebate for these dual eligibles, and when Part D was adopted, suddenly that rebate ended and the prices of those drugs went up so that the Medicare Program paid a much higher price. It was a sweetheart deal. It resulted in a substantial drug manufacturer windfall at taxpayers' expense.

My bill would reverse that windfall, adding drug a manufacturer rebate so that Medicare Part D prices are no higher than prices in programs like Medicaid.

Do you have any thoughts on this rebate bill?

Mr. BLUM. Well, I think the President supports the legislation. In his last budget, the President proposed a very similar change to your legislation, to enable the Part D Program to receive better prices for drugs that were previously paid much less when the beneficiaries received their benefits through State Medicaid Program.

Mr. WAXMAN. I would not interfere in any way with any of the drugs that people would get, it would just mean a huge savings for those drugs, restoring the price we pay for those drugs that the manufacturers received prior to Part D.

We have heard a lot of concern about Medicare beneficiaries, and I know that, Mr. Chairman, your side of the aisle talks a good game when it comes to being concerned about Federal spending. I would like to suggest that our committee look at this opportunity, take action, and pass this bill, Medicare Drug Savings Act, which would cut beneficiary costs, protecting seniors, make sure they have access to drugs.

Mr. Blum, I have heard a great deal about CMS' discussion of the noninterference provisions in the proposed Part D rule. Part D statute states, "Secretary may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors; and may not require a particular formulary or institute a price structure for the reimbursement of covered Part D drugs."

So we have a witness that has gone on to suggest that your rule rests on a questionable legal foundation, it violates the intent of the Congress. I would like to understand this proposal a little better. Does your proposal rule interfere with negotiations between drug manufacturers and pharmacies?

Mr. BLUM. No.

Mr. WAXMAN. Does your rule interfere with negotiations between drug manufacturers and PDP sponsors?

Mr. BLUM. No.

Mr. WAXMAN. Does your rule require a particular formulary?

Mr. BLUM. No.

Mr. WAXMAN. Does your rule institute a particular price structure?

Mr. BLUM. No.

Mr. WAXMAN. So it would seem to me that your rule does not do anything that the Part D statute prohibits you from doing, yet the mere specter of the word "noninterference" has set some industry groups ablaze.

Could you briefly explain what your rule does in this area? My understanding is that the proposed rule merely states that what-

ever prices are, they all have to be reported consistently, is that correct?

Mr. BLUM. Correct. I think we want to make sure that we are clear when and won't the agency will become involved in how Part D plans operate. As I expressed earlier, we often get pulled into disagreements, contract disagreements, contract disputes. Our principle is to make sure that Part D plans honor the requirements, that they have to have complete pharmacy networks, complete pharmacy access standards, but to me and to the agency, this proposed change clarifies what we believe the clause should mean in operations, to us that work to strengthen the requirement, not weaken it, but we have no intention to interfere in the price negotiations between Part D stakeholders.

Mr. WAXMAN. Thank you. Thank you, Mr. Chairman.

Mr. PITTS. Chair thanks the gentleman. Now recognize the gentleman, Dr. Burgess, 5 minutes for questions.

Mr. BURGESS. Thank you, Mr. Chairman. And, Mr. Blum, thank you, and thank you for being here.

If I understood correctly in your comments to Chairman Pitts, you said that costs are going down. You extolled some of the virtues of the Part D Program, and then in the next breath you said some of the fastest growth is projected to be in the Medicare Part D Program.

It reminds me of the old line from the Marx Brothers movie: "Who are you going to believe, me or your own eyes?" So it almost can't be both ways. One or the——

Mr. BLUM. Well——

Mr. BURGESS. One or the other has got to be true.

Mr. BLUM. Let me clarify, please. So looking back, Part D has cost the taxpayers, cost beneficiaries less than what CBO and the CMS actuaries projected back in 2003. That is true, and that is a great statement for us to make together, and a reason to celebrate Part D's success.

When you look at CBO's current projections for the future, not the past but the future, Part D total spending, not just the Part D premium but all the pieces that the program pays, the low-income subsidy, the reinsurance, that is the fastest-growing part of the program.

Mr. BURGESS. Correct. But you just have to ask, what is that based on? So let me ask you——

Mr. BLUM. Why do you—you know the answer to that question.

Mr. BURGESS. Let me—well, let me ask you. When you have this proposed rule that is some 700 pages, that I assume that you have read and approved——

Mr. BLUM. Yes.

Mr. BURGESS [continuing]. Is that correct?

Mr. BLUM. Correct.

Mr. BURGESS. Can you provide the committee with the cost analysis that you did for this rule?

Mr. BLUM. Sure. By requirement, we have to do an economic estimate. This rule was significant, so per OMB process, we put our estimate——

Mr. BURGESS. Have you provided that to the committee?

Mr. BLUM. That is part of the rule.

Mr. BURGESS. OK. Have you provided it already, or is it coming?

Mr. BLUM. We are happy to send a copy of the rule to you.

Mr. BURGESS. Let me ask you this. In that, is there also going to be the delineation of the legal justifications for proposing the rule?

Mr. BLUM. The proposed rule went through our general counsel. They cleared it. We are happy to answer any questions regarding their legal views regarding the regulation.

Mr. BURGESS. Well, let us—and we need that. I mean it is critical to our discussion.

On the noninterference that has come up several times this morning, the noninterference policy, the cornerstone of the Part D Program, under the proposed rule, CMS reinterprets this part of the statute, asserting the language of the law does not apply to negotiations between pharmacies and prescription drug sponsors. So in my mind, there is some confusion as to why, after 10 years, your agency felt that it must now reinterpret the noninterference clause.

What has changed that propelled you to make this distinction?

Mr. BLUM. Well, I think we interact with our Part D plan sponsors on a day-to-day basis. We approve, we review, we have a very rigorous process——

Mr. BURGESS. Do you have evidence to which you can point and provide to this committee why——

Mr. BLUM. We are happy to do that.

Mr. BURGESS [continuing]. You have changed?

Mr. BLUM. Yes, we are happy to do that.

Mr. BURGESS. I would ask you to submit that for the record, and how do you anticipate how the Center for Medicare and Medicaid Services intervention in these negotiations to improve the program. What is your expectation of improvement, can you provide that to the committee?

Mr. BLUM. Absolutely.

Mr. BURGESS. Are you aware of the requirements within the oft-mentioned Affordable Care Act, are you aware of the requirements to keep the proprietary contract terms confidential? That is Section 3301 of the PPACA. And it seems to me it would be contrary to the policy you are proposing in the Part D proposed rule.

Mr. BLUM. We are happy to review that section of the statute to make sure that we are consistent.

Mr. BURGESS. And again, I would—you need to do that and it needs to be detailed.

Let me just ask you again about, were you or Administrator Tavenner or Secretary Sebelius, did you receive any legal memoranda, was any legal memorandum prepared for you that provided you the ability to proceed forward with this rule?

Mr. BLUM. I am not sure about legal memorandum.

Mr. BURGESS. Well, let me restate that to the proposed noninterference interpretation.

Mr. BLUM. So let me be clear. All major regulations go through rigorous review through the department. That includes our general counsel staff. The general counsel cleared the regulation, which means they believed that CMS had the authority——

Mr. BURGESS. And had you received a memorandum to that effect?

Mr. BLUM. I don't know, but I can check for you, sir.

Mr. BURGESS. We need, the committee needs that.

Let me just ask you, were there any doctors on the panel that evaluated the immunosuppressant drugs relative to the proposed protected class?

Mr. BLUM. The CMS chief medical officer for Medicare was part of the panel. And——

Mr. BURGESS. So is that——

Mr. BLUM [continuing]. By the way, he was the same chief medical officer that helped design the Protected Classes back in 2005.

Mr. BURGESS. Well, was there—has there been any breakthrough or change in the science on immunosuppressant drug treatments since 2005 that many of us on the committee might have missed?

Mr. BLUM. Well, I think we recognize the very strong views of patient groups, physician groups. We understand this is a significant change.

Mr. BURGESS. Mr. Blum, I am going to run out of time. With all due respect, it is not just strong views, you give the wrong immunosuppressive, you lose the graft. This may be a graft that has been given a living donor, or someone who donated that upon their demise, but you reject a graft. That is a big deal, and it costs you at CMS a ton of money to then put that kidney patient, graft recipient back on dialysis after they reject their graft, or worse, then pay for another transplant some point down the road. I mean that is an incredible inefficient use of funds. So it is hard for me to believe that you really have the cost benefit analysis in hand when this type of behavior is allowed to go on at CMS.

Thank you, Mr. Chairman, for your indulgence. If the gentleman wishes to respond, but I will yield back.

Mr. BLUM. I pledge that the agency will carefully review both the clinical arguments and the concern from patient classes regarding the changes to the Protected Classes. We understand this is a change. We understand that there are clinical implications, and we will take a very careful look at the comments and the thoughtful arguments coming to us during the comment process.

Mr. PITTS. Chair thanks the gentleman. Now recognize the gentleman from Texas, Mr. Green, 5 minutes for questions.

Mr. GREEN. Thank you, Mr. Chairman, and thank you, Mr. Blum, for being here.

I understand that some plans have used significant incentives, for example, zero cost sharing, to steer patients to the mail-order pharmacies, and I believe patients, of course, should be able to choose the pharmacy setting that best meets their needs, whether it be mail-order or bricks and mortar; however, CMS found that these incentives caused increased demand for mail-order prescriptions, sufficient to disrupt timely delivery of prescriptions to patients. In a retail setting, the beneficiary often was notified of a problem with a prescription in real time, or within hours, but when it happens with a mail-order, the time it takes to find, communicate, and resolve the problem may delay the delivery date and resulting in gaps into the therapy.

I believe that timely access to medicines are critical for patients, and I understand CMS is proposing to establish requirements for timely fulfillment of prescriptions from mail-order pharmacies, as

well as for home delivery services and retail pharmacies. This would provide consistent expectations for beneficiary access to drugs.

Mr. Blum, when you proposed these standards for the timely delivery, did you come up with these standards, or were these guidelines already in existence that you used to develop your proposed standards?

Mr. BLUM. Well, I think we looked at common standards for any kind of mail-order program. We believe strongly that we should have both pharmacy networks and mail-order options for our beneficiaries, that both should provide value to our beneficiaries and provide clear standards. We want to make the options stronger for our beneficiaries, to work better for our beneficiaries, we want to make sure that beneficiaries understand the benefits of preferred pharmacy networks, community pharmacies and mail-order pharmacies, to ensure that both the beneficiaries see clear benefits from different delivery options, but also the taxpayers. And I think more importantly, we want to make sure that plans operate with consistent standards.

We receive complaints from beneficiaries regarding the timeliness, the accuracy of drugs being shipped to them by mail. We think it is appropriate for all plans to compete on a level playing field to ensure that they're providing consistent care and consistent delivery to our beneficiaries.

Mr. GREEN. OK. Beneficiary groups are strongly supportive in ensuring timely access to their needed medicines, whether provided by a pharmacy counter or the mail-order. Could you further elaborate on the proposal and the ruling why CMS believes this is an important beneficiary protection to pursue?

Mr. BLUM. Well, I think we, right now, have standards for pharmacies to fulfill drugs in a timely manner. We believe that similar kinds of timely standards are appropriate for mail-order pharmacies as well, and we want to make sure that beneficiaries receive timely delivery. We want to make sure that we have clear standards, but our goals simply are to provide uniformity throughout how the benefit is delivered, and to ensure that plans compete in a transparent way.

Mr. GREEN. OK. Mr. Chairman, those are my only questions, and I will be glad to yield back.

Mr. PITTS. Chair thanks the gentleman. Now recognizes the gentleman from Illinois, Mr. Shimkus, 5 minutes for questions.

Mr. SHIMKUS. Thank you, Mr. Chairman. Mr. Blum, it is good to see you again. We have worked together before, and welcome.

I go to schools a lot and they talk about the Constitution, and so these questions are meant just as a position of a constitutional basis of what's Article One, which is Article Two. And the basic premise, even I taught government history, was that the administration enforces law. That is the job of the administration. So these questions are posed based upon a real concern out there in America that this administration does not enforce the law, or picks and chooses which pieces of the law they want to enforce.

So let me begin with stating that, as you know, the statute clearly states that CMS may not interfere with negotiations, and I

quote, "between drug manufacturers and pharmacies and PDP sponsors."

I was here, as a few of us were, when Part D was passed. That was an intentional to put that in the law, to ensure that CMS would not interfere with any of these three parties.

Can you tell me why CMS has chosen, based upon this proposed rule, to go against the law as Congress intended?

Mr. BLUM. Well, I think on a practical basis, and overseeing the Part D Program on a day-to-day basis, we constantly or frequently get asked to intervene in contract disputes by plans, by hospitals, by pharmacists. And so we don't necessarily always feel that we can simply say no, we are not going to interfere when beneficiary access is a concern. We have no interest to negotiate prices between Part D plans and pharmacies and drug manufacturers, but on a day-to-day basis, particularly when a——

Mr. SHIMKUS. Well, let me—and I appreciate that, but wouldn't it be a better response if you feel the need to do that, than to have someone sponsor a piece of legislation and correct the law?

Mr. BLUM. Well, I think we——

Mr. SHIMKUS. I mean constitutionally. I mean just——

Mr. BLUM. Yes——

Mr. SHIMKUS [continuing]. In the real world of how we teach our kids, that would be the correct answer.

Mr. BLUM. Well, I am not a constitutional lawyer, so I can't speak to that process with authority, but what I can articulate is the day-to-day challenge of how we operate the program, how we get drawn into individual disputes. We are open to the best ways to——

Mr. SHIMKUS. Well, let me follow on because I have two more questions that just kind of follow on with this.

In the original final Part D regulations published in 2005, CMS separately responded to comments on its original proposed regulation as follows: "As provided in Section 1860D–11(i) of the Act, we cannot intervene in negotiations between pharmacies and Part D plans." And again, in the same document, as provided in Section 1860D–11(i) of the Act, "we have no authority to interfere with the negotiations between Part D plans and pharmacies, and, therefore, cannot mandate that Part D plans negotiate the same or similar reimbursement rates will all pharmacies."

So if that was the ruling from CMS based upon the law, how can the agency today say it is not unlawfully interpreting the noninterference clause, when CMS clearly stated in 2005 that it does not have the authority to negotiate between plans and pharmacies?

Mr. BLUM. Well, I think two points, Congressman. One, we are happy to provide our legal justification to this committee as to how we got to our proposal. But second, the 2005 regulations were drafted at a time before CMS had experience with reviewing, negotiating and approving competing Part D plans.

When I was on the Senate Finance Committee, I think the working assumption would be only a handful of the standalone Part D drug plans would choose to provide coverage. The good news is we have many, many entities wanting to provide drug coverage to our beneficiaries. We have more plans wanting to come into the program every year. And I think the operational realities, the com-

plexities of day-to-day negotiations and interactions with the agency and partners created us—or caused us to take this proposal.

Mr. SHIMKUS. Let me finish with this. In the preamble discussion and the final regulation issued in April 2010, CMS stated the noninterference provisions in Section 1860D–11(i) of the Act explicitly provides that the Secretary may not interfere with the negotiations between pharmacies and PDP sponsors, which would include payment negotiations between the party sponsors and pharmacies for MTM services.

Mr. Blum, you were director of the Center for Medicare, and had operational authority over the Part D Program in 2010. Why did you—why did your interpretation of noninterference change——

Mr. BLUM. Well, I think——

Mr. SHIMKUS [continuing]. Four years later?

Mr. BLUM. I mean, I think with more experience, with more, you know——

Mr. SHIMKUS. But again, that is a debate on the law.

Mr. BLUM. Well——

Mr. SHIMKUS. The law is pretty clear.

Mr. BLUM. Well, we understand the concerns regarding the legality of the provision. We are happy to provide our justification. What I can say is that the complexity to oversee this benefit has, you know, caused us to reinterpret certain——

Mr. SHIMKUS. You are not tasked to reinterpret the law. You are tasked to follow the law.

Thank you, Mr. Chairman. I yield back.

Mr. PITTS. Chair thanks the gentleman. Now recognizes the gentleman, Mr. Barrow, 5 minutes for questions.

Mr. BARROW. Thank you, Mr. Chairman. And thank you, Mr. Blum, for being here.

Mr. Blum, for seniors, Medicare is kind of like home; when you have to go there, they have to take you in. When it comes to prescription drug benefits, Medicare Part D is like home; when you have to go there, they have to take you in. So I want to take stock of what positive has happened before we assess the cost of the benefits to seniors, to our customers, as opposed to the institutional interests that you all have.

First of all, why do you think the program is costing less than it was originally projected to? What is your number one—what is the number one takeaway we get from you as to why the program is costing less than projected?

Mr. BLUM. Well, I think there are many reasons why the Part D Program has cost less than the 2003 projection. I think the first reason is that the Part D Program pays for many more generic drugs today than I think CBO or the CMS actuaries projected back in 2003. I think Part D private plan competition also has caused the Part D premium growth to stay moderate, but I think the number one reason is the fact that we have many more generic drugs provided through the Part D Program than projected back in 2003 by CBO and the CMS actuaries. But——

Mr. BARROW. Referring to your secondary consideration, more competition than anticipated, does that also have a role in this; the fact that some folks are providing generics and others aren't? Isn't that——

Mr. BLUM. Well, I think there are——

Mr. BARROW [continuing]. A little cause and effect there?

Mr. BLUM. Well, I think there are three, you know, kind of primary reasons. The first is, you know, due to the fact that we have fewer new blockbuster brand-name drugs today on market than I think what the actuaries, CBO, projected back in 2003. I think the second reason is Part D private plan competition. Plans compete very hard for their members, which is why we do not agree that Part D premiums will skyrocket due to some changes in how we oversee Part D plans. And third is, the agency is a much more rigorous reviewer of Part D bids and benefit plans coming into CMS. CMS negotiates vigorously with Part C plans, Part D plans, but I think the number one reason that both CBO and CMS actuaries would cite why the costs are lower than projected back in 2003 is the fact that we have fewer new blockbuster brand-name drugs than was previously the case back in 2003.

Mr. BARROW. All right, we have taken stock of how we got here, now I want to take stock of where this—how the—where you want to take us.

Let us talk about the costs and the benefits of the proposed rule. I heard in response to previous questioning that your understanding—your cost benefit analysis is in the rule. I want to focus for a second on the costs and benefits to our customers, as opposed to the cost and benefits to CMS as the—the institutional interests you all have in managing the program the way that you all think it ought to be managed.

Can you tick off for me just what you think of the principle costs to seniors of the direction you all want to take us in? What is going to be the impact as far as they are concerned?

Mr. BLUM. Well, I think we look at costs in kind of multiple ways. One, we want to make sure that the premiums, Part B premiums, Part D premiums, remain—growth remains tempered. The Part B premium has been flat and for the first year has, I think, come down, which is due to the changes passed by the Affordable Care Act. The Part D premium in the last several years has stayed flat. We also want to make sure the cost sharing that beneficiaries pay——

Mr. BARROW. Well, but my point is it stayed flat without taking the direction that you all want to take us in. Do you see foresee any kind of cost impact to the customers as a result of the proposed rule?

Mr. BLUM. Well, I think we should look back at CMS changes over the past 4 or 5 years.

In 2010, we required plans to offer no more than 3 plans, you know, coming down from 5, 6, 7 of benefit offerings down to 3. We heard arguments from the same entities that we hear from today that premiums will skyrocket, when, in fact, they didn't, they stayed flat. So we don't see, based upon prior experience, that, when going from 3 plans down to 2, particularly with the Part D doughnut hole being filled in, that we will see——

Mr. BARROW. Well, I am asking you whether or not there have been any—there are any adverse impacts to seniors, to our customers, as a result of the proposal you all are making, and I am hearing you say none. What are the proposed benefits that you

think the seniors are going to get out of the proposed changes you all want to make?

Mr. BLUM. Well, I think they will see greater clarity, they will have greater confidence that the program is doing everything we can to reduce provider fraud. They will——

Mr. BARROW. That is more of an institutional interest than a customer interest.

Mr. BLUM. Well, I think our customers have an interest to make sure that the program doesn't pay inappropriately.

Mr. BARROW. Sure, but they want to make sure that they are going to have the full range of options they have got too, and they want to make sure they are not going to lose out on this as——

Mr. BLUM. Well, here——

Mr. BARROW [continuing]. In some other way.

Mr. BLUM. Well, here is the past 5 years. We have more sponsors than ever before wanting to come into the program. For 2015, we continue to see more plan sponsors wanting to come into the program to expand benefits, consistent with the past trends. We have heard arguments since the Affordable Care Act that the changes due to the Affordable Care Act would reduce plan premiums, when, in fact—I am sorry, would raise premiums. They have come down by 14 percent.

So I think we have to look at the past 5 years in order to make judgments regarding the future.

Mr. BARROW. Mr. Chairman, thank you very much. I would like to follow up on this but my time has expired.

Mr. PITTS. The Chair thanks the gentleman. Now recognizes the gentleman from Pennsylvania, Dr. Murphy, 5 minutes for questions.

Mr. MURPHY. Thank you, Mr. Chairman.

Despite the success of Medicare Part D, CMS proposed a rule last month that would threaten the health and wellbeing of our most vulnerable seniors: those with mental illness.

Now, having authored the Helping Families in Mental Health Crisis Act, which is H.R.3717, cosponsored by many members of this committee, it codifies protected class status for antidepressant and antipsychotic medications. And having written to Administrator Tavenner on this issue last month, I am deeply concerned that the agency's proposal will have huge, unintended consequences.

Now, this is not one of cost-saving or convenience, it is not about swapping generic and brand drugs. Apparently, a panel is what advised you on making these changes, and some consultant. Do you have a list of the panel members who made this decision?

Mr. BLUM. We can provide it. They were CMS career physicians and pharmacists.

Mr. MURPHY. Psychiatrists?

Mr. BLUM. I don't know, but I can check for you, sir.

Mr. MURPHY. I see. I would think that psychiatric medication, some decision would be made by a psychiatrist.

So these are career people, so they work where?

Mr. BLUM. Within CMS, but I want to also clarify——

Mr. MURPHY. Are they practicing physicians?

Mr. BLUM. I am not sure, but one thing I want to also clarify is that our analysis is on the Web. We proposed the change in an open way, and we understand——

Mr. MURPHY. No, I read the analysis, and it does not say who did it, and it has very limited things.

So let me offer you something. So is it true that, in terms of the proposed rule, there were things from the APA Practice Guidelines that said the effectiveness of antidepressant medications is generally comparable between classes and within the class of medications? You know that is what the register wrote, are you aware of that?

Mr. BLUM. Yes.

Mr. MURPHY. OK. Is it your view that drugs covered in Medicare Part D 6 protected classes are interchangeable?

Mr. BLUM. I think—our clinical review is that some of the drugs are today and——

Mr. MURPHY. I—no, I didn't ask—well, let me go on. Did you validate your findings with the American Psychiatric Association?

Mr. BLUM. We proposed these changes in an open way. We are going to listen very carefully to comments from all medical societies.

Mr. MURPHY. Including the National Association on Mental Illness——

Mr. BLUM. We will—I plan——

Mr. MURPHY [continuing]. And the National Council for Behavioral Health?

Mr. BLUM [continuing]. Tomorrow—we will work very carefully with both the clinical patient communities to ensure that our——

Mr. MURPHY. How about the National Institute on Mental Health?

Mr. BLUM. We are happy to meet with all stakeholders.

Mr. MURPHY. Now, I have in my hand a letter here from the American Psychiatric Association, and I want to read you a couple of quotes from this. It says, "We find it particularly disturbing that CMS used selective and improper references to APA Treatment Guidelines as justification for limiting coverage of these medications." The letter goes on to state that "selective quoting from our guidelines and flawed clinical logic apparently led CMS to conflate the supposed 'interchangeability' of drugs within the classes of both antidepressants and antipsychotics with overall evidence for efficacy when this is just one element of a drug's appropriateness for an individual patient."

Were you aware that CMS selectively quoted from the APA?

Mr. BLUM. Well, I think one of our principles, sir, was to make sure that we——

Mr. MURPHY. Yes or no——

Mr. BLUM. We——

Mr. MURPHY [continuing]. Were you aware?

Mr. BLUM. We wanted to make sure that our analysis was public, detailed——

Mr. MURPHY. I see. There is a letter in front of you. You have that letter?

Mr. BLUM. Yes.

Mr. MURPHY. There is a highlighted section.

Mr. BLUM. Sure.

Mr. MURPHY. Could you read that out loud?

Mr. BLUM. "CMS also cited the APA Treatment Guidelines in support of its claim that there is a 'lack of unique effects for distinguishing individual drug products when initiating drug therapy' and that treatment guidelines ... generally do not advocate preference of one SSRI drug over another for initiation of therapy. CMS' conclusion is not supported by the evidence it cites. It misinterprets and misrepresents APA's clinical practice guidelines multiple times as justification for limiting patient access to" the necessary products.

Mr. MURPHY. Exactly. So it is important. I mean, you are going back then for a comment, but you didn't list them in the first place.

Do you know what an SSRI is?

Mr. BLUM. I have been advised.

Mr. MURPHY. Do you know how long it takes for one to take effect?

Mr. BLUM. Not personally, but I have been advised.

Mr. MURPHY. About 2 to 4 weeks, and yet there is a standard here if it doesn't have an impact on someone's hospitalization within 7 days, it can be disregarded.

Do you know that according to the National Alliance on Mental Illness, that seniors who died by suicide, 20 percent of them do it the day of their doctor's appointment, 40 percent the week of their doctor's appointment, and 70 percent the month of their doctor's appointment? So psychiatrists and their patients know that not all medications are created equal. Each one is in a different therapeutic, or within a therapeutic class have different molecular makeups, different side effects, different drug-drug interactions, they impact a person's brain in unique ways, which is why physicians and patients with serious mental illness often try different therapies until they find the right one that works.

If you restrict access to these drugs, you restrict the treatment of mental illness, you impact increasing hospital stays, you raise suicide rates among a population that has an increased suicide rate once people reach 65, and you restrict and you forbid the use of life-saving drugs.

On behalf of the mental health community, I urge CMS to reconsider, because senior citizens with schizophrenia, bipolar illness or depression, this is a matter of life and death. So I want to ask you, will you commit to removing this unscientific, callous, and antimedical decision that will lead to harm for seniors with mental illness?

Mr. BLUM. Sir, I will commit to making sure that our policy is right for patients.

Mr. MURPHY. Sir, you are not a physician. You are the people's worst fears. You have no background, no education, no training, and it sounds like the people in this panel are not practicing physicians either and not psychiatrists. You are practicing medicine without a license. This cannot stand. For people who are at high risk for depression and suicide and mental illness, I urge you to go back and remove this rule.

Thank you. I yield back.

Mr. PITTS. Chair thanks the gentleman. Now recognize——

VOICE. [Inaudible.]
Mr. PITTS. Without objection, so ordered.
[The information follows:]

Submitted by Rep. Murphy

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February 25, 2014

The Honorable Fred Upton
Chairman
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U.S. House of Representatives
2125 Rayburn House Office Building
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The Honorable Henry A. Waxman
Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives
2322A Rayburn House Office Building
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The Honorable Joe Pitts
Chairman
Energy and Commerce Health Subcommittee
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone, Jr.
Ranking Member
Energy and Commerce Health Subcommittee
U.S. House of Representatives
2322A Rayburn House Office Building
Washington, DC 20515

Dear Representatives Upton, Waxman, Pitts and Pallone:

I write on behalf of the American Psychiatric Association (APA), the medical specialty association representing approximately 35,000 psychiatric physicians and their patients and families, to express appreciation for your convening this important hearing on recent proposed rulemaking from the Center for Medicare and Medicaid Services (CMS) regarding the Medicare Part D program. APA is deeply concerned about the proposed rule's potential impact on the well-being of Americans who suffer from mental illness that will be created by limiting Medicare patients' access to medically necessary pharmaceutical treatments.

Currently Medicare Part D beneficiaries have coverage for all or substantially all medications in six protected classes of pharmaceuticals that are prescribed to treat conditions including mental illness, epilepsy, cancer, and HIV/AIDS. Recent proposed rulemaking from CMS would remove antidepressants and antipsychotics from the protected classes, leaving those with severe and persistent mental illness, i.e. the most medically vulnerable elderly and disabled individuals who often suffer from multiple comorbid medical conditions, without medically appropriate treatment options to address their disease.

We are especially troubled that CMS used the criterion that drugs in a category must not be clinically interchangeable (as defined by this proposed rule) to support the elimination of antidepressants and antipsychotics from the protected classes. We find it particularly disturbing that CMS used selective and improper references to APA Treatment Guidelines as justification for limiting coverage of these medications so essential for the treatment of Medicare beneficiaries with mental illnesses

CMS misrepresents APA's relevant practice guidelines. In the proposed rule it provides a quote taken out of context, "the effectiveness of antidepressant medications is generally comparable between classes and within classes of medications," to support its proposed limited coverage for these drugs. The full quote leads to a very different conclusion:

> Because the effectiveness of antidepressant medications is generally comparable between classes and within classes of medications, the initial selection of an antidepressant medication will largely be based on the anticipated side effects, the safety or tolerability of these side effects for the individual patient, pharmacological properties of the medication (e.g., half-life, actions on cytochrome P450 enzymes, other drug interactions), and additional factors such as medication response in prior episodes, cost, and patient preference. [1]

In other words, the choice among antidepressants should be made on the basis of a variety of important factors including tolerability of side effects, precisely because all antidepressants are not comparable in these respects. The selective quoting from our guidelines and flawed clinical logic apparently led CMS to conflate the supposed "interchangeability" of drugs within the classes of both antidepressants and antipsychotics with overall evidence for efficacy, when this is just one element of a drug's appropriateness for an individual patient.

CMS also cited the APA Treatment Guidelines in support of its claim that there is a "lack of unique effects for distinguishing individual drug products when initiating drug therapy" and that "treatment guidelines ... generally do not advocate a preference of one SSRI drug over another for initiation of therapy." CMS's conclusion is not supported by the evidence it cites. **It misinterprets and misrepresents APA's clinical practice guidelines multiple times as justification for limiting patient access to medically necessary psychotropic medications.**

APA guidelines that address the use of antidepressants and antipsychotics, including the guidelines on major depressive disorder, anxiety disorders, schizophrenia, and obsessive compulsive disorder, all recommend the opposite of CMS's interpretation. They recommend that choice of medication must be made on the basis of how a drug's unique effects may interact with a patient's individual situation. This includes such factors as gender, pregnancy status, age, ethnicity, co-occurring psychiatric conditions, and other co-occurring medical conditions. These unique drug effects include different mechanisms of action, pharmacological properties (e.g., drug-drug interactions), side effects, and safety concerns.

In addition to concerns about drug interactions for patients with comorbid medical and psychiatric conditions, there is tremendous individual variation in patients' ability to tolerate side effects. For example, one antipsychotic class drug may give a patient with schizophrenia parkinsonian side effects like tremors, stiffness, and drooling. A different drug may cause weight gain. Another option could control hallucinations and delusions *without* these side effects for this patient. Given the challenge and importance of medication adherence in patients with psychiatric illnesses, all APA practice guidelines emphasize the importance of considering a patient's individual needs and preferences when choosing an antidepressant or an antipsychotic.

APA strongly recommends that both antidepressants and antipsychotics remain categories of clinical concern on Part D formularies. We are currently preparing our full response to CMS's proposed rule, and will shortly share this with you upon its completion. Thank you again for

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[1] *Practice Guideline for the Treatment of Patients with Major Depressive Disorder, Third Edition*, pg17 http://www.psych.org/practice/clinical-practice-guidelines

looking into this critically important issue. The leadership and members of APA look forward to working with you to better our patients' access to needed psychiatric services and the most clinically appropriate pharmacological interventions.

Sincerely,

Saul M. Levin, M.D., M.P.A.
CEO and Medical Director

TIM MURPHY
18TH DISTRICT, PENNSYLVANIA

COMMITTEE ON ENERGY AND COMMERCE
CHAIR, OVERSIGHT AND INVESTIGATIONS
ENVIRONMENT AND ECONOMY
HEALTH

CO-CHAIR, STEEL CAUCUS
CO-CHAIR, MENTAL HEALTH CAUCUS

WEBSITE: murphy.house.gov

Congress of the United States
House of Representatives
Washington, DC 20515

January 14, 2014

Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Ave., S.W.
Washington, D.C. 20201

Dear Administrator Tavenner,

I write today concerning the recent proposal by the Centers for Medicare and Medicaid Services (CMS) to reduce coverage of mental health drugs in the Medicare Prescription Drug Benefit, or Part D program, by eliminating designation of those therapeutic categories of medications as so-called "protected classes." Having authored the Helping Families in Mental Health Crisis Act (H.R. 3717), which codifies protected class status for antidepressant and antipsychotic medications, I am particularly interested in this issue and the Agency's proposal.

The protected classes were put into place in 2006 to ensure Medicare beneficiaries in the Part D program had access to life-saving doctor-prescribed medication. At the time, your Agency designated six such classes based upon the correct understanding that medications in each class were chemically distinct and not interchangeable. In fact, the current Part D Manual states that "CMS instituted this policy because it was necessary to ensure that Medicare beneficiaries reliant upon these drugs would not be substantially discouraged from enrolling in certain Part D plans, as well as to mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations."

Given your Agency's extensive history on this issue, and the understanding that access to "all or substantially all" medications in the protected classes were needed by Medicare beneficiaries, I was dismayed to learn that CMS is proposing to remove depression drugs from the protected classes, and is considering the same change for antipsychotic medications in 2015. The seriousness of your proposal, and the unexplained change in the Agency's thinking, is of grave concern to me and millions of senior citizens relying on access to these medications.

The Proposed Rule fails to address the Agency's past acknowledgement that Medicare beneficiaries require access to medications in therapeutic classes where different drugs are not interchangeable. The CMS proposal appears not to be grounded in a concern over beneficiary health. Instead, the proposal seeks to increase profits through increased rebate-negotiating leverage for private Prescription Drug Plans Sponsors or insurers (known as PDPs), which received federal subsidies to participate in the Part D program. To the extent that CMS addresses beneficiary concerns, the Agency asserts that beneficiaries are at-risk from "profitable" drug manufacturers, which have an incentive to promote "off-label" usage. This rationale is made without a factual basis, but even if it were to be true, eliminating Medicare beneficiary access to medications is not the solution to this problem.

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Within days of the Agency's proposed rule, CMS also published a study demonstrating that the very anti-depression drugs CMS proposes removing from protected class status had equivalent, if not higher, generic utilization in Part D than the mean for all drugs in the program.[1] This data undermines the Agency's suggestion that a problem exists in ensuring access to less expensive anti-depression medications, and indicates that notwithstanding their protected class status, these medications are being appropriately prescribed and used in the Part D program. The Agency's own data on generic utilization rates indicates there is no problem to address.

To better understand both the Agency's current thinking about protected classes and the specific proposal to remove mental health drugs from protected class status, I ask that you provide by no later than January 28, 2014, written answers to the follow questions:

1. Please describe the Agency's current medical rationale for designating therapeutic categories of medications as a "protected class." More specifically, please explain whether Medicare beneficiary health and the interchangeability of drugs within a therapeutic class continue to be the Agency's primary considerations for designating medication categories as a "protected class."

2. Please explain the basis upon which CMS concluded clinical concern justifying protected class status arises only "if access to drugs within a category or class for the typical individual who is initiating therapy must be obtained in less than 7 days..." such that "failure to initiate the therapy within that time period would be likely to lead to hospitalization, incapacity, disability or death as a result of the exacerbation of the disease or condition to be treated." In particular, I request that you address the evidence supporting the Agency's view that denial of access to clinically distinct depression medications would not lead to hospitalization, incapacity or disability during a one week period. The Agency should provide me with a detailed explanation of the medical literature it considered in making this important determination on the health and wellbeing of Medicare beneficiaries.

3. Please provide any evidence supporting the Agency's view that "the profitability of products not subject to normal price negotiations as the result of protected class status is a strong incentive for the promotion of overutilization, particularly off-label overutilization, of some of these drugs." In your response, please provide specific examples of the drugs to which you refer, and what factual evidence, as opposed to anecdotal evidence, you have to support this view.

I appreciate your prompt attention to this request. If you have any questions, please contact Brad Grantz in my office at (202) 225-2301.

Sincerely,

Tim Murphy
Member of Congress

TM:bdg

[1] Shiengold, et al., Impacts of Generic Competition and Benefit Management Practices on Spending for Prescription Drugs, Evidence from Medicare's Part D Benefit Medicare and Medicaid Research Review 2014:4(1) at E1 (2014), available at: http://www.cms.gov/mmrr/Downloads/MMRR2014_004_01_a01.pdf

Mr. PITTS. The Chair now recognizes the gentlelady from Virgin Islands, Dr. Christensen, for 5 minutes for questions.

Ms. CHRISTENSEN. Thank you, Mr. Chairman, and thank you, Mr. Blum.

I have a similar question to begin with. We have had many issues with CMS over N-stage renal disease patients and the regs that have been changed over the years. Were there any transplant physicians who served on the panel?

Mr. BLUM. I don't believe so, but again, CMS proposed these changes in an open, transparent way. We walked through every detail of our analysis, and we welcome feedback, we welcome disagreement to ensure that we get the policy right.

Ms. CHRISTENSEN. Well, given the risks to this vulnerable population, which make up a large part of the CMS-covered—especially Medicare, covered population, it—doesn't—if they do not receive the appropriate immunosuppressant medication, doesn't CMS think it is important for a transplant physician who has experience treating patients with varying organ transplants to weigh in on how clinical practice guidelines should be interpreted?

Mr. BLUM. We agree that CMS should do everything possible to make sure that patients receive the drugs prescribed to them, that meet their clinical needs. I think it is important to recognize that we pay for about 140 drug classes, and while we have 6 protected, we don't hear the concerns regarding lack of that kind of patient access—however, we deeply recognize and deeply appreciate the concerns from patient groups, physicians, and we pledge to make sure that we listen, we understand, and to have our final policies best serve patients.

Ms. CHRISTENSEN. And we appreciate that. My experience is that clinical guidelines are an important reference for physicians to use to identify the treatments with the strongest evidence base, but that they are indeed a guide and the decisions and immunosuppressant drug regimens and psychiatric medications must be tailored to the individual patients' needs, and this decision is best made by the transplant physician who really knows the medical history of the patient.

I have a question that I also need to ask. CMS is proposing to make changes to the number of enhanced plans that can be offered by any one sponsor, and to the number of contracts a sponsor can have in a bid region. I want to ask about this proposed requirement.

I have seen one industry-sponsored study that says 7 million beneficiaries will be affected, a letter by the chairman notes that more than 8 million will be affected, another industry-sponsored study cites 14 million people who will be affected. The number seems to be growing like Pinocchio's nose. On the other hand, organizations representing Medicare beneficiaries are strongly supportive of the proposed two-plan requirement. They believe it strengthens the program for beneficiaries, making choices more meaningful and making sure plans aren't gaming the system.

So I would like to provide you with the opportunity to discuss these proposals. My first question is why did CMS believe it was important to address these issues, and rationalize the number of

plans that can be offered in an area? Was the agency seeing gaming?

Mr. BLUM. Well, I think one game that we have seen right now, or that the program is now experiencing, is that some plan sponsors offer what they call enhanced coverage, that is actually coverage far cheaper than their basic benefits. And that is a strategy to select healthier beneficiaries to lower-cost plans.

Now, that may be good for the program, but on the other hand, what happens is that the low-income beneficiaries who are auto-assigned to that higher-premium plan, if the program pays the full premium cost, that costs the government, not saves the government. So we need to take a balanced look at how plan structures are being offered to ensure they best serve beneficiaries, they are not confusing, but they also lower total program costs——

Ms. CHRISTENSEN. Let me try to get a——

Mr. BLUM [continuing]. In our program.

Ms. CHRISTENSEN [continuing]. A couple—thank you for that clarification. Could you comment on how the Federal Government taxpayers and plans—well, I guess you did, with dual eligible beneficiaries are paying more than they should because of the way the plan sponsors are offering multiple plans in that area. Did that pretty much address that question?

Mr. BLUM. Well, I think dual-eligible beneficiaries pay the same copayment. They are fixed in statute, but the Medicare Program pays just about the complete cost of those drugs, not based upon a set fee schedule, but based upon the prices negotiated by the Part D plans. We want to make sure that we are paying the right, correct, fair rates on an apples-to-apples basis with the Part D plans.

Ms. CHRISTENSEN. And some of us cited this proposal will hurt dual eligible beneficiaries in the basic plans, but I interpret it exactly oppositely. Some enhanced plans with dual eligibles are not enrolled and may be consolidated with other plans, but dual eligible will benefit from lower costs in the basic plans that they enroll in. If I could just get an answer to that. Is that correct?

Mr. BLUM. Well, I think we want to make sure that when plans provide what is called enhanced coverage, that it is more generous than their basic plan offerings; one, so beneficiaries clearly understand what it means to sign up for coverage that is enhanced, but also to make sure that when the program is paying the complete cost, the full premium, that we are not paying more than what we should if the plan structures were more consistent.

Ms. CHRISTENSEN. Thank you, Mr. Chairman, for allowing the answer.

Mr. PITTS. Chair thanks the gentlelady, and now recognizes the gentleman from Virginia, Mr. Griffith, 5 minutes for questions.

Mr. GRIFFITH. Thank you, Mr. Chairman. I appreciate that.

Let me start off by saying that I am concerned when you keep saying, you know, you can provide us with the legal status memorandum. This appears to be a major controversy as to whether or not this—these changes are legal, and most of the folks up here believe that it is not legal, particularly when it is so large a change. And I will have to tell you, this is what happens when one agency goes rogue. It wasn't yours, but, you know, I dealt with the Solyndra situation, as many people up here did, and general coun-

sel there did not give legal—good legal advice, in my opinion. They gave bad legal advice, the agency acted on it, and I think they violated the law not once, but about 3 times. And that was my opinion after reviewing all of the documents involved, and all the opinions involved, is they got bad counsel. So I am going to ask you to get a second opinion after you provide us with what you already have from your legal counsel, I am going to ask that perhaps you look at getting a second opinion because this is a very serious matter, and it appears that the legality is in serious question.

Now, that being said, I have a little bit different tack, because last year, based on conditions in my district, I asked you all to do something, and that was to take care of our pharmacies. And I have recently had a conversation with one of my pharmacists who is willing to accept the price negotiated in the region, you know, just let me be able to provide my customers with the drug that they need, or the drugs that they need, and he has been told no. And so when you say to us today that you are getting a lot of complaints, I understand that.

Now, my question is last year I wrote a letter, and I am going to write you another letter, thanking you all for taking care of the community pharmacies, and saying, hey, if you meet the price, you can do it, because I represent a mountainous district, it may not be the big mountains they have in the west, but in the east we have some pretty good mountains in southwest Virginia. And so if you don't have a preferred pharmacy, you might be in the same county, but you might not be in an area where my people can get there easily, particularly if we happen to have 20 inches of snow on the ground, it is going to be even more difficult to travel those 10, 20, 30 miles that may pile up to get to the next pharmacy that is on the list. And so I do appreciate what you all did in that regard.

Question becomes whether or not you have a legal basis to do it.

Now, under your theory, with what you are changing in this rule, and, of course, it is not the whole 800 or 700-and-some pages, and I do have serious questions about the rest of it, you are trying to take care of that situation, you are trying to make it so that my constituents can go to the pharmacy down the street instead of having to drive around the mountain to the next pharmacy over, isn't that correct?

Mr. BLUM. So I think a couple of things. We want to make sure that we are proposing these changes in an open and transparent way. And so one of the benefits is that, going through the notice and comment process, we get the best legal advice, not just from our lawyers but from the Congress, from outside stakeholders.

And so to your first point about getting a second opinion, that is precisely why we chose to go through the notice and comment process.

To your second question regarding the pharmacists protections, we believe that Part D plans should be able to offer tiered pharmacy networks. We see evidence that they do reduce costs for the program, for beneficiaries, but we have two principles. Principle one is that beneficiaries need to benefit from those tiered pharmacy networks. It can't just be the plan sponsor that benefits, but it has to benefit both the beneficiaries and the taxpayers. And we agree

that tiered pharmacy networks need to be fair, not just to the plan, not to the beneficiary, but to the community pharmacists. And so we have a hard time seeing the data evidence that we are seeing today, that the evidence for cost savings is mixed, and telling community pharmacies, well, they can't participate with major Part D plans. We want those tier pharmacy networks to be fair, we want to make sure that beneficiaries see clear savings, but we agree that preferred pharmacy tools can be a good tool for the Part D program if structured correctly.

Mr. GRIFFITH. And here is the concern you are hearing today. Look, I think if you are fair to the beneficiaries, and I want fairness as well, if you are fair to the beneficiaries then you are being fair to the community pharmacists because, in most cases, particularly in the rural areas, the folks know their pharmacists, they want to go to that pharmacist, and they go to somebody who is close by, and they want to make sure they don't have to drive around the mountain to get to the other side of the mountain in order to get their drugs, because it may not look like much on a map, but it is a big deal when you are having to drive that. But I have to say, you know, Mr. Shimkus was right earlier when he said the whole idea is if you don't have the authority, it doesn't matter how much fairness you want, you need to bring that to us, and you need to say we need a bill to make this fair. And if what I need to do to take care of my people is to introduce a bill, then I will do that, but let us make sure that we don't have the Constitution being set aside because it is inconvenient.

I yield back.

Mr. PITTS. Chair thanks the gentleman. Now recognizes the gentlelady from California, Mrs. Capps, 5 minutes for questions.

Mrs. CAPPS. Thank you, Mr. Chairman. And Deputy Administrator Blum, thank you for your testimony today.

I believe this proposed rule has some serious problems, but it also includes some important steps forward to ensure that future CMS decisions are based on the best data available. But today's hearing shows that it is important for us to be cautious as we evaluate ways to make this program more sustainable and efficient.

One area that I would like to add my voice of concern is in the proposal to eliminate some of the protected classes of prescription drug coverage. You know, I have been a public health nurse for too many years in my community, and I understand that access to the right treatment at the right time is very critical for some of our most vulnerable groups, and I have grave concern that if this rule is proposed, it could put that in jeopardy. This is especially important as many of the ailments that would lose this status are said common—morbidities affecting perhaps many more individuals than we might think. And while I have concerns about access for vulnerable populations due to that part of the rule, I do want to applaud the agency for another change that will also have an important impact for improving care for patients, and that is the enhanced eligibility criteria for Part D medication therapy management, the MTM Program.

I welcome CMS' recognition of the importance of MTM that it plays in increasing medication adherence, improving healthcare

outcomes, and reducing overall program costs. Specifically, the proposed rule would lower the threshold for beneficiary eligibility, meaning that an additional 16½ million beneficiaries could be able to benefit from this important service.

My question is, would you outline the specific benefits that you envision this expansion will deliver to beneficiaries as well as to the Part D Program, just so we get that on the record?

Mr. BLUM. Well, one of the things that we know is that there are greater opportunities to assist beneficiaries, to ensure they stay compliant, to help manage complicated polypharmacy regimes. Our team sees growing evidence that the MTM Programs can help to improve drug compliance, can lower overall costs of the program. We agree that a well-designed Part D benefit works not only to improve patient care, but to lower total program costs. And so our goal is to expand the availability of these programs to more beneficiaries, to ensure more beneficiaries get the benefits of these programs.

Mrs. CAPPS. Thank you. And, you know, clearly, there have been some concerns about the policies in this and other proposed rules. Maybe it is a lack of understanding, maybe it is just the complexities of the issues, but one of the main concerns we hear from supporters and opponents of changes proposed by CMS is that the data is not accurate. The proposed rule we are discussing today seems to get at some of those data discrepancies by requiring uniform standards for reporting negotiated drug prices across Part D sponsors, but I know that some groups are concerned that this could interfere with negotiations regarding drug prices with pharmaceutical manufacturers. It is a very complicated arena, but would you now expand on CMS' intent for this particular aspect of the proposed rule? What is the goal of this portion of the rule, and how do you think this is going to affect price negotiations, which, after all, is the bottom line?

Mr. BLUM. Well, I think a couple of things, Congresswoman. The Part D benefit is not a purely capitated program where CMS simply pays a premium to plans and lets the plans negotiate prices. There are other payment mechanisms built within the Part D Program. There are risk corridors, reinsurance, catastrophic coverage, the fact that for many low-income beneficiaries, dual eligibles, the program pays just about the entire cost of the drug bill.

Now, we have no interest or no policy desire to interfere with the negotiations between Part D drug plans and pharmaceutical manufacturers, but we believe that those prices should be reported, kind of in a consistent way, to make sure the program is paying fairly, and if the Part D plan is benefitting from the lower negotiated price, and given the large size of the premium costs, the cost sharing, the catastrophic coverage, the reinsurance, the risk corridor, that those prices should be paid—should be reported in a consistent way to ensure those discounts not just get retained by plans, but get passed on to beneficiaries and to the taxpayers that are funding the vast majority of the program costs.

Mr. PITTS. Chair thanks the gentlelady. Now recognizes the gentlelady from North Carolina, Mrs. Ellmers, 5 minutes for questions.

Mrs. ELLMERS. Thank you, Mr. Chairman. And thank you, Mr. Blum, for being with us today.

Mr. Blum, I think it is important that you know that over a half a million seniors in North Carolina will be affected by these proposed rules, and I just want to start off by stating that fact.

I am a little concerned with the interpretation that you—CMS has on not interfering or arbitrating or mediating between pharmaceutical companies and manufacturers. You are basically coming in and saying, "We are not going to be in the middle, what we are going to do is take over and dictate." Is that not essentially what you are doing?

Mr. BLUM. I don't see any desire or attempt for us to dictate the negotiation of prices between Part D plans and providers, manufacturers. We believe in private plan competition, we believe in choice, but choice that is fair to beneficiaries and fair to the taxpayer.

Mrs. ELLMERS. OK, and you have stated that, and you are basically reiterating what I said, but essentially what you are saying is you are going to come in and control the situation as a whole, kind of as a whole umbrella effect——

Mr. BLUM. That is not what I said——

Mrs. ELLMERS [continuing]. Of control.

Mr. BLUM [continuing]. Congresswoman. What I said is that we get pulled into disagreements between plans, pharmacies, other entities. And so our view is this clarification helps to strengthen the noninterference, to describe precisely how we interpret it on a day-to-day basis, but from a day-to-day basis, CMS continuously gets pulled into disputes——

Mrs. ELLMERS. OK. Well, let us move on. Let us move on. The CMS rule proposed that prescription drug plans are limited to offering only one standard benefit and one enhanced benefit. Is this correct?

Mr. BLUM. That is correct.

Mrs. ELLMERS. So essentially, 50 percent of the plans that are available now will be decreased and eliminated?

Mr. BLUM. I think, a couple of clarifications. The first is, this is a continuation and a continuous pathway for us to reduce the number of enhanced plans. There are only 2 percent of Medicare beneficiaries that are in that category of plans that could be eliminated——

Mrs. ELLMERS. But——

Mr. BLUM [continuing]. If CMS chose to finalize the proposal. When CMS moved from 5 plans down to 3 plans, we heard the same concerns, the same arguments, that premiums would skyrocket, that beneficiaries would go without coverage, they would have to change plans. And as we have heard, you know, throughout this hearing, the Part D premium has stayed constant, has stayed flat. So we need to be concerned regarding the comments and the criticisms coming to us regarding this change, but we also have to look on the past 4 or 5 years to really make a complete judgment regarding this proposed change.

Mrs. ELLMERS. OK, well, there again, to your point that you are making, you are basically justifying the reasoning behind eliminating, as you pointed, only 2 percent of these patients receive the benefit from what is being eliminated, correct?

Mr. BLUM. I am trying to give the justification for CMS' proposal. This is still on comment, and we have——

Mrs. ELLMERS. And this is——

Mr. BLUM [continuing]. Made no policy——

Mrs. ELLMERS [continuing]. From a perspective of trying to save dollars in healthcare, is that correct?

Mr. BLUM. I think our total estimate, if the proposed change is completed, is that it is overall savings, small but overall savings, and we are also trying to make the benefit work better for our beneficiaries.

Mrs. ELLMERS. Do you realize, though, that the changes that are being made to Medicare Part D will then actually increase the spending in Medicare Part A and Part B, because many times these patients will then be rehospitalized, sent to the hospital for care?

You cited in part of your justification at the beginning the vulnerabilities, one of which has to do with the protected classes of drugs. Nursing home patients being a large patient body that receives those medications, that is an ongoing issue. Have you ever been to a nursing home before?

Mr. BLUM. Yes, I have. And, also, we understand that the nursing home industry is also very concerned regarding the high rate of use, and the high degree of variability in antipsychotic use——

Mrs. ELLMERS. OK, so would it not be more efficient, then, to go to the source? You cited overprescribing of medication. Wouldn't it make more sense to narrow down who it is that is overprescribing drugs than it would be to eliminate the entire program?

Mr. BLUM. Well, I think we have—Congresswoman, we have worked very closely with the nursing home industry——

Mrs. ELLMERS. OK, I only have one more moment, because it is not the nursing home that prescribes the drug, it is the physicians that prescribe the drugs. So I want to make that clarification. In relation to the potential impact on seniors, because of any willingness provider provision, staff of the Energy and Commerce Committee spoke with the Office of the Actuary, who told them, "Any time you make a network wider, costs go up." Can you respond to that? Because you have just told me that this is an effort at decreasing cost.

Mr. BLUM. I agree that pharmacy networks have the potential to lower costs for the program for beneficiaries. In our current program today, we see strong evidence that pharmacy networks do reduce costs. We also see evidence that some pharmacy networks in their current forms don't lead to cost savings for our beneficiaries and for the program.

Mrs. ELLMERS. So, basically, what you are saying is a direct complete——

Mr. BLUM. What I am saying is——

Mrs. ELLMERS [continuing]. Opposite opinion of the——

Mr. BLUM. No, that is not what I am saying.

Mrs. ELLMERS [continuing]. Office of the Actuary.

Mr. BLUM. What I am saying is that we believe that pharmacy networks, if structured correctly, make clear to beneficiaries the pros and cons of preferred pharmacy networks versus not, they do reduce cost, but the data right now shows that some pharmacy net-

works in their current forms don't reduce costs for beneficiaries. Our goal is to make sure that preferred pharmacy networks work, and work well for beneficiaries, but also work well for——

Mrs. ELLMERS. Thank you. I——

Mr. BLUM [continuing]. And——

Mrs. ELLMERS [continuing]. Have gone way over my time——

Mr. BLUM [continuing]. And for the——

Mrs. ELLMERS [continuing]. So I appreciate——

Mr. PITTS. The Chair thanks the gentlelady. Now recognizes the gentlelady from Florida, Ms. Castor, 5 minutes for questions.

Ms. CASTOR. Well, I want to thank you, Chairman Pitts, for calling this Oversight hearing for Medicare Part D, and thank Mr. Blum who is here from the Center for Medicare and Medicaid Services, and thank everyone at CMS for working to improve Medicare Part D, helping to simplify it for beneficiaries, make benefits more meaningful and cost-effective for everyone. But it has to be balanced by science, and I think that many of the many advocates for beneficiaries and those who have chronic illnesses and other sicknesses have very valid points about the Protected Class Policy.

So I want to make sure everyone is aware; this is a proposed rule, this is what CMS has proposed in January, correct?

Mr. BLUM. Correct.

Ms. CASTOR. And there is an open comment period where you can receive comments from people all across the country, whether they are medical, professionals, beneficiaries, family members, pharmacists, is that correct?

Mr. BLUM. That is correct, Congresswoman, and we pledge to meet with all stakeholders on this issue to understand comments and concerns, and this is proposed and we pledge to talk to clinicians, beneficiary groups to ensure that——

Ms. CASTOR. And the comment period is——

Mr. BLUM [continuing]. We get the policy right.

Ms. CASTOR [continuing]. Open until when?

Mr. BLUM. I believe March 10, March 14.

Ms. CASTOR. OK. Mr. Blum, many private insurance plans steer patients toward preferred pharmacy networks and mail-order pharmacies in an attempt to lower costs, but CMS has found that total drug costs were not consistently lower in preferred pharmacy networks, and, in fact, the retail pharmacies in the nonpreferred network were actually offering savings to the Medicare Trust Fund through discounted generics at prices below those offered by pharmacies with preferred cost sharing.

And I hope you have reviewed the research done by the National Community Pharmacist Association. The community pharmacists chose one commonly purchased prescription drug plan, and entered in the Medicare plan finder for the most frequently prescribed drugs; the generic version of Lipitor, the generic version of Plavix, Diovan and Nexium. The costs were then compared between preferred, mail-order and nonpreferred pharmacies in 9 cities across the country, and according to the analysis, I think it is quite surprising, 89 percent of the time preferred pharmacy costs to Medicare were higher than those of nonpreferred pharmacies, and 100 percent of the time, mail-order costs to Medicare exceeded those of nonpreferred pharmacies.

Now, this is really counterintuitive to how you think it would work. How can Medicare be paying more for mail-order and more for drugs at preferred pharmacies? Medicare is supposed to be benefitting from competition here that will bring prices down, and it is troubling that plans are offering little to no savings in the aggregate in their preferred pharmacy pricing, particularly in mail-order for generic drugs. So instead of passing on lower costs available through economy scale of deeper discounts, a few sponsors are actually charging the program higher prices. So preferred networks and mail-order pharmacies should save the patient and the Medicare Program money, I would think.

So I would like to ask you first, is the situation I have described where mail-order and preferred pharmacies are costing Medicare more than community pharmacies, similar to what CMS found in your analysis of Part D?

Mr. BLUM. Thank you for the question.

First, to clarify. The comment period for the proposed rule closes March 7. I apologize for not giving the accurate answer.

To your question regarding preferred pharmacy networks. I think the reason why CMS proposed this change was that we saw similar data results. When you look at the actual cost of the drug being paid by the program, being paid by the beneficiary through cost sharing, there is not a consistent pattern that preferred pharmacy networks, mail-order, lead to consistent lower prices for beneficiaries, for the program. And we want to make sure that our Part D plans have all the cost containment tools that they can use to lower costs, benefit beneficiaries, benefit taxpayers, but when the program is permitting plans to restrict some pharmacies to not participate within their networks, we believe the principle should be that we need to demonstrate there is savings to our beneficiaries, to our taxpayers.

So we embrace preferred pharmacy networks so long as they are fair to beneficiaries, they are fair to pharmacists, and they are fair to the taxpayers that fund the vast majority of the cost of the program.

Ms. CASTOR. So you would agree that it is inconsistent with the Part D law that preferred networks would cost Medicare more money?

Mr. BLUM. I think the intent of the program is to ensure that Part D plans have tools to lower costs, not just the premium, but cost sharing, reinsurance payments, risk corridor payments, and that should be the principle that the Medicare Program follows.

Ms. CASTOR. Thank you very much. I have nothing else.

Mr. PITTS. Chair thanks the gentlelady. Now ask consent to submit for the record three letters: one from the National Association of Chain Drug Stores, one from the American Society of Transplantation, and one from the Association of Mature American Citizens.

Without objection, so ordered.

[The information follows:]

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

Statement

Of

The National Association of Chain Drug Stores

For

U.S. House of Representatives
Committee on Energy and Commerce
Subcommittee on Health

Hearing Entitled:

"Messing with Success: How CMS' Attack on the Part D Program Will Increase Costs and Reduce Choices for Seniors"

February 26, 2014
10:00 a.m.

National Association of Chain Drug Stores (NACDS)
1776 Wilson Blvd., Suite 200
Arlington, VA 22209
703-549-3001
www.nacds.org

The National Association of Chain Drug Stores (NACDS) thanks the Members of the Subcommittee on Health for consideration of our comments for the hearing entitled "Messing with Success: How CMS' Attack on the Part D Program Will Increase Costs and Reduce Choices for Seniors." NACDS and the chain pharmacy industry are committed to partnering with Congress, the Centers for Medicare & Medicaid Services (CMS), patients, and other healthcare providers to improve the quality and affordability of the Medicare program.

We are currently reviewing CMS's recently issued proposed rule regarding "Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs." To respond to CMS, we are drafting written comments, and would be pleased to provide copies to the Subcommittee Members when completed. At this time, however, we would like to share with the Committee comments of interest for the hearing.

NACDS represents traditional drug stores and supermarkets and mass merchants with pharmacies. Chains operate more than 40,000 pharmacies, and NACDS' 125 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ more than 3.8 million individuals, including 175,000 pharmacists. They fill over 2.7 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 800 supplier partners and nearly 40 international members representing 13 countries.

Introduction: Value of Pharmacy

NACDS believes that pharmacists play a vital role in advancing the health, safety and well-being of the American people. As the face of neighborhood healthcare, community pharmacies and pharmacists provide access to prescription medications and over-the-counter products, as well as cost-effective health services such as immunizations and disease screenings. Through personal interactions with patients, face-to-face consultations and convenient access to preventive care services, local pharmacists are helping to shape the healthcare delivery system of tomorrow – in partnership with doctors, nurses and others.

As an organization representing healthcare companies that create and support millions of jobs in the U.S., we understand the importance of reducing and controlling our nation's mounting debt, and we offer our solutions as to how pharmacy can add value and save money for the nation. In recent years, retail community pharmacies have played an increasingly important role in providing patient care. For example, pharmacists promote cost savings by improving medication adherence through medication management therapy (MTM), expanding the proportion of Americans that are immunized and increasing the use of generic drugs.

Medication Therapy Management (MTM): Better Outcomes and Lower Costs

Pharmacists have the ability to improve medication adherence. The costs of poor adherence are staggering, costing the U.S. approximately $290 billion annually, 13% of total healthcare costs.[1] These unnecessary costs fall disproportionately on government programs such as Medicare and Medicaid, which cover approximately 30 percent of all prescription drugs

[1] New England Healthcare Institute, 2009

dispensed in this country. The experiences of Part D beneficiaries, as well as public and private studies, have confirmed the effectiveness of pharmacist-provided MTM.

A recent report by CMS found that Medicare Part D beneficiaries with diabetes, congestive heart failure (CHF) and chronic obstructive pulmonary disease (COPD) who were newly enrolled in the Part D MTM program experienced increased medication adherence and discontinuation of high-risk medications. According to the report, patients with CHF and diabetes had nearly $400 to $525 in lower overall hospitalization costs than those who did not participate in the Part D MTM program. The report also found that MTM can lead to reduced costs in the Part D program as well, showing that the best performing plan reduced Part D costs for diabetes patients by an average of $45 per patient.

A *Health Affairs* article from July 2013 reported the findings of a study demonstrating that targeting efforts to improve medication adherence, especially among people who are high users of healthcare services, and increasing Medicare Part D enrollment in MTM could improve health and lower costs. The study found that poor medication adherence was associated with additional medical and hospital visits resulting in otherwise avoidable spending for Medicare Part A and B services in the range of $49 to $840 per beneficiary per month. In addition, the study demonstrated that aligning MTM eligibility with a metric such as potentially preventable future costs holds promise for both improving the quality of care and reducing spending.

Moreover, how and where MTM services are provided also impacts effectiveness. A study published in the January 2012 edition of *Health Affairs* identified the key role of retail pharmacies in providing MTM services. The study found that pharmacy-based intervention programs increased patient adherence for patients with diabetes and the benefits were greater for those who received counseling in a retail, face-to-face setting as opposed to a phone call from a mail order pharmacist. The study suggested that interventions such as in-person, face-to-face interactions between the retail pharmacist and the patient contributed to improved behavior with a return on investment of 3 to 1. Policymakers have begun to recognize the vital role that local pharmacists can play in improving medication adherence. The role of appropriate medication use in lowering healthcare costs was recently acknowledged by the Congressional Budget Office (CBO). The CBO revised its methodology for scoring proposals related to Medicare Part D and found that for each one percent increase in the number of prescriptions filled by beneficiaries there is a corresponding decrease in overall Medicare medical spending. When projected to the entire population, this translates into a savings of $1.7 billion in overall healthcare costs, or a savings of $5.76 for every person in the U.S. for every one percent increase in the number of prescriptions filled.

NACDS Model PBM Legislation

NACDS has promoted state model legislation that we believe will contribute to maintaining patient access and reducing barriers to care, particularly for beneficiaries who reside in rural areas or face cultural or linguistic challenges. Community pharmacies meet patients' needs

for convenient access through a highly competitive environment that gives consumers choices in how their medications and healthcare services are provided.

We believe that imposing narrow pharmacy networks would restrict patient freedom to patronize the business of their choosing and the knowledgeable professionals that play a critical role in providing care and cost savings. People who take prescription medications regularly, manage chronic diseases, use emerging pharmacy services, and who are older have even stronger positive opinions about access to their own pharmacy.

NACDS has also promoted with our model legislation in the states the need for honest and transparent pricing. We believe prescription drug pricing standards are vital and that regular updating of pricing lists and notification of changes are imperative. Transparency in pricing determinations helps providers have a clear understanding of the standard benchmarks that will be used in establishing the cost of a drug. This allows for proper business planning and can help alleviate the impact of acquisition cost swings in the generic drug market that have occurred recently. The ability to address any volatility in drug cost pricing is essential to the success of pharmacies.

In addition to supporting transparency in pricing determinations, NACDS also has promoted initiatives to require fair and honest dealing with pharmacies with respect to appeals processes for challenging pricing determinations. Finally, in our model legislation we have supported measures to ensure that pharmacies are not subject to unfair pharmacy audits. Audits are intended as tools to seek out and eliminate fraud, waste, and abuse. However, pharmacies

have been forced to endure audits that impose inordinate penalties for minor oversights and technical miscues.

Conclusion

We thank you for your leadership on these critically important healthcare issues and look forward to working with you as the nation seeks to address the fiscal challenges before it.

February 18, 2014

The Honorable Marilyn B. Tavenner, Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-4159-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: Transplant community opposition to CMS proposal to remove Immunosuppressive medications from Medicare Part D Protected Class category

Dear Administrator Tavenner:

The American Society of Transplantation has serious concerns regarding the proposed rule to remove immunosuppressant medications for transplant rejection prophylaxis as a protected class under Medicare Parts C and D. Our understanding is that the decision to target immunosuppressive drugs is per the recommendation of the CMS Protected Classes Review Panel.We strongly disagree with the Panel's determination that CMS will no longer require every drug product to be included on every formulary. We point out that the Panel recognizes, and we agree, that timely access to immunosuppressants is critical for patients with transplanted organs. Indeed, long-term success is only possible when the host immune response is continuously and effectivelysuppressed. Our point here is that inability to access the proper medications and combinations will lead to increased rates of chronic immune rejection characterized by organ injury, patient suffering and ultimately even death. We are certain that CMS will recognize that any decision with such a negative impact on an entire class of vulnerable patients is not correct.

The key point is that current immunosuppressive therapies in transplantation are based on the use of multiple drugs whose mechanisms are complementary. We create a level of effective immunosuppression by drug combinations, not by a single agent. Each agent has different toxicities and each drug effects the action and efficacy of the other agents in the combination. For example, within one class, a requirement to substitute cyclosporine for tacrolimus, can result in a 40% reduction in mycophenolate exposure and/or a five-fold increase in sirolimus exposure, requiring changes in multiple drugs and frequent additional monitoring. Thus, it is simply impossible to safely switch back and forth between individual drugs in the combinations without completely reevaluating the whole combination.

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The bottom line is that forcing physicians to constantly make such fundamental changes to life-saving immunosuppression would dramatically and negatively impact the entire transplant care model. As already noted, the impact would be entirely to the detriment of a vulnerable patient population. It will dramatically increase the need and costs for constant drug level monitoring. It will increase the number of necessary patient visits to evaluate the changing therapies that not only cost the program and payors but also the patient's employers in lost productivity and time. Consider simply the reality of a single transplant physician trying to constantly monitor what drugs are available to hundreds of individual patients typically being seen only a few times per year in the transplant center. Consider the impossibility of responsibly managing immunosuppressive therapy over the many years our patients live with their transplants, change jobs, move around and change the workflows of their care.

We strongly support the efforts of CMS to reduce health care spending and improve patient care. However, this particular proposal to prevent the accessibility of our patients and physicians to all the current immunosuppressive drugs in every formulary would not achieve either reduced health care spending or improved patient care. In the strongest possible terms, we state that this proposal will dramatically increase health care costs, profoundly damage the care and health of our transplant patients, and lead to significant patient and family suffering as the result of reducing organ survival.

Therefore, we strongly urge you to rescind the proposed rule and continue to maintain the current protections for access to all or substantially all immunosuppressive drugs for Medicare Part D beneficiaries.

Sincerely,

Daniel R. Salomon M.D.

Daniel R. Salomon, MD
President, American Society of Transplantation

Amac
Association of Mature American Citizens
Voice of Americans 50+

February 25th, 2014

The Honorable Joe Pitts
16th District, Pennsylvania
420 Cannon House Office Building
Washington, DC 20515

The Honorable Frank Pallone, Jr.
6th District, New Jersey
237 Cannon House Office Building
Washington, DC 20515

Dear Chairman Pitts and Ranking Member Pallone,

On behalf of the 1.1 million members of the Association of Mature American Citizens (AMAC), I am writing to express our deep concern regarding newly proposed regulations for the Medicare Part D prescription drug program and how they may negatively impact the health care coverage of mature Americans and seniors.

AMAC is in favor of leaving the Medicare Part D market-based, public-private partnership between drug manufacturers and health plan sponsors in its current structure. The majority of medication costs have already come out of the Part D program due to the generic status of the many maintenance drugs that are commonly prescribed. Generic drug usage dominates throughout the program and provides many choices for both physicians and patients. If anything, interference by the Centers for Medicare and Medicaid Services in the Part D program – particularly with protected class medications – could limit access to drugs and sharply reduce choice.

As a champion of free market solutions, AMAC remains concerned that these new regulations will unnecessarily expand the government's role in the Medicare Part D program, ultimately leading to unnecessary burdens and costs to providers and consumers. AMAC is also concerned that the proposed regulations appear to conflict with the intent of Part D as it was originally written, and deliberately circumvent Congressional processes.

AMAC strongly opposes attempts by the Administration to exert more control over valued programs like Medicare Part D that already work efficiently and effectively and enjoy significant popularity among older Americans.

As the fastest-growing seniors' advocacy organization in the country, AMAC remains committed to ensuring that mature Americans are able to maintain access to the cost-effective Medicare Part D benefits they prefer. Thank you for your concern and attention to this critical matter.

Sincerely,
Dan Weber
President and Founder of AMAC

Mr. PITTS. Now the Chair recognizes the gentleman from New Jersey, Mr. Lance, 5 minutes for questions.

Mr. LANCE. Thank you, Mr. Chairman.

Good morning to you, Mr. Blum. I will be concentrating on what I believe is an overreach by the department, and I understand when the law was written, there was a debate whether there should be negotiations involving the Federal Government, but as I read the law, that was clearly decided in the statutory law and I am deeply concerned at what I believe is the illegal reading of the law by the agency.

My concerns go not only to this situation but to several other situations where the administration has unilaterally delayed the ACA. I think the administration should have come to us in Congress with statutory change, recess appointments argued before the Supreme Court several weeks ago. I believe the Supreme Court will rule those recess appointments were unconstitutional. EPA regulation under the Clean Air Act, argued before the Supreme Court earlier this week. Now, that is not your purview, any of those matters, I understand that, but you are here this morning regarding the topic under discussion.

There is a legitimate debate in this country; whether or not there should be negotiations by HHS, I understand that, but the noninterference provision is, in my judgment, unambiguous that that is not the right or the responsibility of HHS, it does not permit negotiations between Part D sponsors and pharmacies. And as I understand what was statutorily created, Senator Grassley stated, for example, that the noninterference provision is at the heart of the bill's structure for delivering prescription drug coverage through market competition. I think that is a good deal for consumers, rather than through price fixing by the CMS bureaucracy.

In the conference report at the time the legislation became law, this is a direct quote, "In order to promote competition, the Secretary is prohibited from interfering with the negotiations between drug manufacturers and pharmacies and PDP sponsors." Between drug manufacturers and pharmacies and PDP sponsors. And yet as I read what has occurred in this proposed rule, prohibits only HHS' involvement in negotiations between drug manufacturers and pharmacies, and between drug manufacturers and PDP sponsors, but under the rule, not prohibiting HHS involvement in negotiations between pharmacies and PDP sponsors. Am I accurate in that?

Mr. BLUM. I think we have clarified how we interpret the noninterference provision of the statute. I agree that they were vitally important to the framework of the 2003 legislation. During my time on the Senate Finance Committee——

Mr. LANCE. Yes.

Mr. BLUM [continuing]. I worked very closely with Senator Grassley's office——

Mr. LANCE. Yes.

Mr. BLUM [continuing]. And so I agree with——

Mr. LANCE. That is why I raised it.

Mr. BLUM [continuing]. The premise. Now, we do not believe that the Part D Program should interfere with price negotiations——

Mr. LANCE. Um-hum.

Mr. BLUM [continuing]. As I said previously, oftentimes Part D plans, pharmacists try to bring the agency into contract disputes. We felt it was important to clarify how we interpret the noninterference clause, but I am very familiar with how it was drafted, very familiar——

Mr. LANCE. Probably more familiar——

Mr. BLUM [continuing]. With——

Mr. LANCE [continuing]. Than I.

Mr. BLUM. Yes.

Mr. LANCE. Well, thank you. Let me say, I think that the current interpretation is novel, and I think it strains statutory credulity. I think it strains the statutory text beyond reasonable limits.

Now, I am an attorney, and I am familiar with the deference doctrine under Chevron, but as I read applicable law, particularly from the DC Circuit and from the Second Circuit, I think this goes well beyond any deference that would be permitted under the Chevron doctrine. And, undoubtedly, this will be litigated if the rules are finalized, and I would urge the administration, based upon sound principles of law, to reconsider this matter, and if a change is required, as is true in so many areas, the ACA, recess appointments, EPA regulations, I urge the President of the administration to come before Congress to seek statutory change.

Thank you, Mr. Chairman.

Mr. PITTS. The Chair thanks the gentleman. Now recognizes the gentleman from Maryland, Mr. Sarbanes, 5 minutes for questions.

Mr. SARBANES. Thank you, Mr. Chairman. Thank you, Mr. Blum, for being here.

I think it is an important undertaking what CMS is doing. I think it is a fair expectation on the part of the taxpayers and the beneficiaries that periodically you kick the tires on the program, even if it is working very well and we are all happy with the track record. I mean when this was first rolled out, there were problems. Democrats who were initially concerned about the program, I think stepped up to try to improve it, and we now have a program that works well and is respected by its beneficiaries. So that doesn't mean that you don't come along every so often and try to make it better, which is what you said.

So we ought to be going through this exercise, and I endorse the process that you have undertaken. The rule—the proposed rule covers a lot of different areas, as you have indicated. I share some of the concerns you have heard with respect to removing the Protected Class for certain categories of drugs, and as you know, there is a broad coalition that has expressed those concerns, and I encourage the agency to pay careful attention to that.

In terms of the requirement to reduce the number of plan offerings, I agree with you, I think that is an important step to consider. I think you are right to point to the alarm that existed the last time you did something like this, and the track record now shows that it has been an improvement overall. And there is still potential for a lot of confusion on the part of seniors and beneficiaries when they look at the plan offerings. So as long as you are not diminishing the quality of the options that are available across the board, I think that that is a reasonable change to pursue.

I share, and you have seen this on both sides of the aisle, concerns on the part of independent and community pharmacists that they are not getting the full benefit and access to some of these preferred networks and so forth, and that is clearly something that the rule is trying to address.

The Medicare Program, the Part D Program, is not permitted to negotiate with drug manufacturers, correct?

Mr. BLUM. Correct.

Mr. SARBANES. But you reimburse plans that are themselves negotiating with those drug manufacturers.

Mr. BLUM. Correct. Part D plans negotiate the formularies and negotiate the prices with manufacturers. It is not true that CMS simply pays a fixed premium to Part D plans. We pay many other separate payments that are based upon the actual prices being negotiated. We don't plan or don't want to interfere in those negotiations. But the 2003 law that was legislated created many separate payment mechanisms that the program pays Part D plans. And, for many beneficiaries, we're essentially a cost-based reimbursement, particularly for the dual-eligible beneficiaries that receive continuity of coverage.

Mr. SARBANES. It is certainly fair for the program to expect that if the plans are securing discounts, that some of that benefit would come back to the program and to the taxpayers. If the program was not doing a reimbursement, if the patient was paying directly to a plan that originally cost $100 for a drug, and the plan was paying the manufacturer $75 and getting a $25 mark-up, but then was able to go negotiate and get that for $50, there would certainly be an outcry on the part of the consumer if none of that savings was being passed through. I think the transparency that the program is demanding in terms of what the drug pricing is and how it works is to get to the notion that taxpayers also have a rightful expectation that, if there are significant discounts being earned by the plans relative to the manufacturers, that some of the benefit of that ought to come back to the program. And that doesn't—that interest on your part in transparency does not translate into interference or trying to negotiate directly with manufacturers, or anything else, that is just basic fair transparency. Is that not right?

Mr. BLUM. Correct, and we believe that competition has served the Part D Program well in the past 10 years. At the same time, we believe that prices reported to the program for purposes of paying cost-sharing assistance or other, you know, kinds of payment mechanisms need to be reported in a consistent way to ensure that competition is fair, to ensure that both beneficiaries and taxpayers benefit from that competition.

Mr. SARBANES. Thank you.

Mr. PITTS. Chair thanks the gentleman. Now recognize the gentleman from Louisiana, Dr. Cassidy, 5 minutes for questions.

Mr. CASSIDY. Hi, Mr. Blum.

Mr. BLUM. How are you?

Mr. CASSIDY. You always know your stuff, man. I don't always agree with you, but you know your stuff, so thank you.

Let us just put it on the table. In your testimony, you mentioned the concerns, recent changes to the MA Program will result in lower enrollment, higher cost appear unfounded, but let us be hon-

est, only a small fraction of the scheduled cuts have come into being, and, indeed, the cuts that were already scheduled were papered over by large grants by CMS. I would note, GAO questioned the legality of those demonstration projects. A cynic would say they were being papered over prior to the last presidential campaign, but far be it for me to accuse the administration of politics.

So given that, I mean you see no basis that these cuts going forward could have an impact on the care that patients are receiving?

Mr. BLUM. So before the Affordable Care Act was signed into law, Medicare paid on average about 13 to 14 percent more than the same cost for the traditional Fee-For-Service Program. Today, we are paying roughly about 103 percent of costs on average, compared to the Fee-For-Service Program. So a dramatic decrease in the total cost that the program paid private plans. That includes the costs to our quality bonus demonstration.

During that time period of dramatically lower premiums——

Mr. CASSIDY. But going—I—not to interrupt, we have limited time, I don't mean to be rude. Going forward, there are further cuts, I think, what, I see J.P. Morgan says that payments will be cut at least 4 percent in 2015, which is more than you suggest, but nonetheless, so the cuts begin to accelerate.

Mr. BLUM. So we estimate that the proposed change that CMS put forward last week for the Medicare Advantage Plans, on average, will be roughly the same change that was finalized for 2014, the current year. For——

Mr. CASSIDY. But without the demonstration projects.

Mr. BLUM. Net, net. So, you know, apples-to-apples comparison.

In 2014, we are on track to exceed our 5 percent growth projection——

Mr. CASSIDY. But let me ask you. Those cuts are in addition to the previous cuts.

Mr. BLUM. So——

Mr. CASSIDY. So you add cuts—you have more cuts, you have more cuts in '16 and more cuts in '17, at some point the cumulative effect, that—saying 3 percent this year is not going to result in any worsening that 3 percent last year, ignores the fact that you had 3 percent last year.

Mr. BLUM. So every year, CMS phases in parts of the Affordable Care Act changes. Every year, we hear that plans will pull out, benefits will be cut——

Mr. CASSIDY. No, no. Now you are dodging the question. The fact is is that you have an accumulation of cuts. So, sure, we can speak about rhetoric and about how, you know, you give grants and somehow it doesn't happen, but there is 3 percent, there is 3 percent, and it accelerates, and to say that it doesn't—that is not going to—I mean are you really maintaining that these cuts are going to eventually have no effect?

Mr. BLUM. I think——

Mr. CASSIDY. Yes or no.

Mr. BLUM. What we are saying is our—what I believe is that the past 5 years we have seen——

Mr. CASSIDY. Never mind. That is fine. I don't mean to be rude but this is clearly a talking point. I don't mean to be rude but I am not getting a yes or no, I am sorry.

Next, one of your things is that you are going to require physicians to be enrolled in Part D in order to participate. Now, I am a doc. I get so sick of bureaucrats telling me how to run my show. There are so many things that already are looking at me. I mean physicians must be one of the most scrutinized people in terms of bureaucracy staring at them. Why are we going to kick our box from the ability to prescribe if they are not a Medicare provider?

Mr. BLUM. Well, I testified to the Senate Homeland Security Committee, based upon reports from the IG that found that the program was paying for prescriptions written by prescribers that were not licensed physicians. We think it is appropriate for us to have the same standard——

Mr. CASSIDY. Now stop. If I may, there are other ways to weed out unlicensed physicians. Do we have to say, OK, you can—if you are licensed, you cannot work for a nursing home in an underserved area, you are not going to be able to work for them, because somebody without a license should be kicked out anyway.

Mr. BLUM. Well, that is the situation that we have today. That is the rule that we have today, that we rely on State pharmacy licensure, and that hasn't worked.

Mr. CASSIDY. Now, I will say that that doesn't mean that now we are going to use, as a surrogate for that not working, another set of regulations. As—speaking for my fellow physicians who are groaning under the burden of paperwork laid upon them by CMS, and thinking about getting out of the system because they are so sick of it, this threatens a senior's access to physician care because CMS doesn't understand that one more piece of paperwork is just enough to make me retire to Florida.

Mr. BLUM. Well, we understand the burdens, but we also——

Mr. CASSIDY. If you do, you are not operationally understanding it.

Mr. BLUM. Well, our principle is to make sure that prescribers who are writing scripts pay for the Part D Program, are licensed——

Mr. CASSIDY. I don't see the rationale for that beyond you don't think other laws are being implemented, being enforced. It seems better to enforce those other laws than add on more regulation.

Mr. BLUM. Well, those are State laws, and I think we feel that we have a responsibility to ensure that the taxpayers that front the vast majority of costs to the Part D Program are paying for prescriptions that are written by legitimate physicians.

Mr. CASSIDY. With that defense of further centralization of healthcare and to the Federal Government, I yield back.

Mr. PITTS. Chair thanks the gentleman. Now recognize the gentleman from Kentucky, Mr. Guthrie, 5 minutes for questions.

Mr. GUTHRIE. Thank you, Mr. Blum. Thank you for coming. I appreciate that.

I just want to first go back to what—I think are questions that Mr. Shimkus and you had. If I heard correctly, which I think I did because I wrote it down, he quoted a 2010 position that CMS had that would not have allowed this rule to go forward, and then you said, and I quote, "reinterpreted the law" to allow this rule to go forward. You also said that you understand the legal concerns that we have, not in that exchange, but you understand the legal con-

cerns that we have, which I would say you understand that, the basis is quite questionable or else you wouldn't understand our concerns if you didn't understand how we could question that. And you say that you have been pulled in by other groups to get involved in negotiations, and you had to come up with this rule because other groups want you to be involved. And I hear from people all the time in my district; veterans, other things that they are in bad situations, and I just have to say to them I wish I could help you, but the law is the law, and it is my job to change the law and fix the law to help you in that situation, but I can't just go reinterpret the law. And that is what you said. And I think all of my colleagues, whether Republican or Democrat, House or Senate, should be really concerned with what you said today; that there could be a position of CMS, you want to do something different so you go back and reinterpret the law on a questionable basis. Or I think that—I just want to put out this—what was said, and I will give you a chance to respond to that if you want to do so, or I can go into my questions.

Mr. BLUM. Well, I think a couple of things. As I said during my opening statement, the Part D Program has many vulnerabilities, and we did a comprehensive review based upon the policy concerns that come to us from members of Congress, stakeholders, partners, and based upon our own operational experience. We chose to propose changes, to talk about our principles, to testify here today to discuss our concerns, to discuss the vulnerabilities that we see.

Mr. GUTHRIE. Well, did you have to reinterpret the law to go forward with this?

Mr. BLUM. We want to invite comment, we want to invite conversation, that we don't believe the status quo for the Part D Program is perfect. There are vulnerabilities. We have to accept that. We have to accept the program is spending $70 billion, the fastest projected——

Mr. GUTHRIE. Well, let me——

Mr. BLUM [continuing]. Program——

Mr. GUTHRIE [continuing]. Just—I only have a—I want to get to the question, but if you have a—if all that is true, and if we accept all that, but that doesn't mean you can just do it without the legislative——

Mr. BLUM. And that is precisely what——

Mr. GUTHRIE [continuing]. Authority.

Mr. BLUM. That is precisely why we go through the notice and comment period. We want to invite a perspective, we wanted to testify before this committee to explain our rationale, to hear disagreement.

Mr. GUTHRIE. But to the legal side. I am not just saying whether the——

Mr. BLUM. Well——

Mr. GUTHRIE [continuing]. Rules are correct or not or——

Mr. BLUM [continuing]. During the comment process, many stakeholders submit legal opinions, law firms submit comments to us to tell us whether we are right or we are wrong.

Mr. GUTHRIE. Well, I don't—but you had to reinterpret the law to get to where you were, that was your quote.

Mr. BLUM. I would call it a clarification, sir.

Mr. GUTHRIE. OK. Well, you—OK, you said—one complaint I don't hear from my constituents is Medicare Part D. I just don't hear from them on Medicare Part D as a problem moving forward. And you did say in your opening statement——

Mr. BLUM. I would invite you to look at the complaint——

Mr. GUTHRIE. I am going to look to your complaints and see, but I don't—when I go to town hall meetings, nobody stands up and says I don't like my drug plan. But—so one of the things you said, you support competition as long as seniors understand. And, you know, that—I imagine going into a superstore and saying here is the aisle limited choices for people that are 65 and older, and here is the rest of the superstore for everybody else. And, you know, it just says, you know, they do understand and it is—the Milliman report says up to 15 percent of Part D plan choices may be eliminated or materially changed during 2015 or 2016, based on provisions in the rules. So some of my constituents will have plans that they chose, plans that they like, and if they like what they have, they can keep it, as we have heard, and I know that when constituents under the ACA were—plans were changed, and people were just saying, well, they were paying for something they shouldn't have paid for because it wasn't worthy insurance. I have heard that even in this committee. And, obviously—so that is just assuming people don't understand what they are buying. And I don't think that is the case. I think people are far more sophisticated and smarter than maybe what those kinds of comments give them credit for.

And so what do I tell my constituents if they can't get plans because they are limited? You said it is only 2 percent, but that is 2 percent.

Mr. BLUM. Well, I think a couple of things. One is we want to make sure that we are incorporating into our final policies the views from the beneficiary communities, beneficiary stakeholders. What we hear from the beneficiary community is that the benefit is confusing. We see from the academic literature that beneficiaries would have the opportunity to reduce their out-of-pocket costs dramatically by changing plans. We want beneficiaries each year to take a critical look at their benefit offerings, because we know that many beneficiaries will be able to save, reduce their out-of-pocket costs. That is why we have private plan choices. We want competition, we want beneficiaries to evaluate and be able to understand the benefits for different plan options, but we know that most beneficiaries year-to-year don't change plans, even though they could benefit dramatically by changing plans.

Part of the reason that we hear from the beneficiary community, and again, we invite this public conversation, is the benefit is confusing. We see plans cherry-picking the healthiest beneficiaries, raising costs for the rest of the program. But we will respectfully review and carefully review comments sent to us to make sure that we are fostering competition, but in a way that helps beneficiaries choose the best possible plan, but also make sure the taxpayers don't overspend. I would hope the Congress would want us to manage the Part D budget in the most prudent way.

Mr. GUTHRIE. Well, thanks. I do appreciate you coming today. Appreciate it, and I yield back.

Mr. PITTS. Chair thanks the gentleman. Now recognizes the gentleman from Georgia, Dr. Gingrey, 5 minutes for questions.

Mr. GINGREY. Mr. Blum, you have been with CMS since 2009, is that correct?

Mr. BLUM. Correct.

Mr. GINGREY. You have been in this current position, number 2 guy, for, what, about a year?

Mr. BLUM. Roughly speaking, yes.

Mr. GINGREY. Yes. And I certainly can understand a new coach coming in, wanting to do something kind of drastic, but quite honestly—and I commend you on the transparency aspect of this proposed rule, but I think the rule is boneheaded. In fact, Bill O'Reilly would probably call it pinheaded.

I would expect, since you have been around since 2009, that you know on, let us say, a 5-year average, the last 5 years, how many participants in Medicare Part D, the prescription drug plan, have reached the doughnut hole, what percentage on average over the past 5 years?

Mr. BLUM. I don't have the numbers in my head, but what is true is many fewer beneficiaries are hitting the doughnut hole because it is being closed.

Mr. GINGREY. Yes, but I suspect that number is pretty low. I am surprised you don't have that. Maybe somebody behind you could whisper in your ear——

Mr. BLUM. We would be happy——

Mr. GINGREY [continuing]. And tell you——

Mr. BLUM. But I believe the numbers are roughly year-to-year——

Mr. GINGREY. Well——

Mr. BLUM [continuing]. And it changes year-to-year, roughly 3 to 4 million Medicare beneficiaries hit the doughnut hole——

Mr. GINGREY. Yes. Yes

Mr. BLUM [continuing]. Each year. However, but——

Mr. GINGREY. I would suggest that, you know, you are trying to kill a gnat by torching a village. You are trying to fix things that are not broken, and to do it, maybe the optics of closing the doughnut hole look great. And so you have to go back and say, well, we are going to look at these Protected Classes, and we are going to do something about that and we are going to save money so we can close the doughnut hole. And look, listen to these 6 drug classes. Antineoplastics, that is cancer, ladies and gentlemen. Anticonvulsants. Maybe we ought to add marijuana to that. Antiretrovirals, that is AIDS drugs. Antipsychotics. Antidepressants. Anti-immunosuppressants. These are people who have had transplants—renal transplants, and if they don't get the drugs necessary within 3 to 5 years—they can't pay for them, and all of a sudden they reject these transplants.

I just, you know, I wish I could tell you that I was shocked at the egregiousness of this proposed rule, and that this was all just a mistake, but that would be too kind.

At this point, we must recognize the pattern of this administration attacking any healthcare program that empowers a free market, no matter the pain it causes beneficiaries. I personally, as a physician, find it reprehensible that the administration is so

against any market-based system, that they are willing to once again harm seniors to serve the purpose. My colleague from Maryland said, you know, every now and then you have to kick the tires to see if a program is working. Well, on the Affordable Care Act, you—every time you kick the tires, your foot goes through the sidewall. So maybe you are a little reluctant, so you kick the tires of a good program and your foot comes bouncing right back in your face. And that is what is going on here. And let us be clear, this proposed rule will destroy the Part D Program as we know it. It will limit our seniors' coverage options, and it will force higher premiums, unwarranted changes to a program where beneficiaries are overwhelmingly satisfied. It just doesn't make sense.

Now, Mr. Blum, even as I disagree with the contents of the rule, I also question whether CMS, you guys, even have the legal authority to reinterpret the clear Congressional intent in the Medicare Modernization Act of 2003. I was here. I was here when that was passed. The Energy and Commerce majority staff requested that CRS review the legality of your actions, and we requested a memo in response. The memo cites, and I will just give you a little bit of it because I am running out of time, a Supreme Court decision that interpreted a statute, a court should always turn first to one cardinal cannon before all others; that a legislature says in a statute what it means, and it means in the statute what it says.

Mr. Blum, Congress has opined on this. Why does CMS feel the need to act at all when the law is crystal clear on this issue?

Mr. BLUM. Well, I haven't seen the CRS reports. I would welcome having a chance to look at it.

Mr. GINGREY. Well, Mr. Chairman, I request unanimous consent that we make this report from the Congressional Research Service on the proposed interpretation of the noninterference provision under Medicare Part D as part of a permanent record. And I will come back to the——

Mr. PITTS. Without objection, so ordered.

[The information follows:]

Congressional Research Service
Informing the legislative debate since 1914

MEMORANDUM February 25, 2014

To: House Committee on Energy and Commerce
Attention: Robert Horne

From: Kathleen S. Swendiman
Legislative Attorney
Ext. 7-9105

Subject: **Proposed Interpretation of the Noninterference Provision Under Medicare Part D**

On January 10, 2014 the Department of Health and Human Services (HHS), Centers for Medicare and Medicaid Services (CMS) published a proposed rule titled "Medicare Program: Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs (Proposed Rule)."[1] In this rule, CMS proposes significant changes in the way it administers several aspects of the Medicare Program's outpatient prescription drug benefit ("Part D") program. The Part D program, which provides coverage of outpatient prescription drugs to Medicare beneficiaries who choose to enroll in this optional benefit, was created pursuant to P. L. 108-173, the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA).[2]

This memorandum provides a legal analysis of the Secretary of HHS' proposed interpretation of Section 1860D-11(i) of the Social Security Act, 42 U.S.C. § 1395w-111(i) which provides as follows:

> **Section 1860D-11(i) Noninterference**
>
> In order to promote competition under this part and in carrying out this part, the Secretary –
>
> (1) may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors; and
>
> (2) may not require a particular formulary or institute a price structure for the reimbursement of covered Part D drugs.

[1] 79 FED. REG. 1918-2073 (proposed January 10, 2014) (to be codified at 42 C.F.R. Parts 409, 417, 422 *et al.*), available at http://www.gpo.gov/fdsys/pkg/FR-2014-01-10/pdf/2013-31497.pdf. Comments on the Proposed Rule are due to CMS by March 7, 2014.

[2] 42 U.S.C. §§ 1395w-101 *et seq.* Prescription drug coverage is provided through private prescription drug plans (PDPs), which offer only prescription drug coverage, or through Medicare Advantage prescription drug plans (MA-PDs), which offer prescription drug coverage that is integrated with the health care coverage they provide to Medicare beneficiaries under Part C. For more information on Medicare Part D and how it relates to other aspects of the Medicare program see CRS Report R40425, Medicare Primer, coordinated by Patricia A. Davis and Scott R. Talaga.

Proposed Interpretation of the Noninterference Provision

In its preamble to the proposed regulations, CMS explains that because of the "many questions that continue to arise," the agency and Part D stakeholders would benefit from a clear, formal interpretation of Section 1860D-11(i) of the Social Security Act (Act), the noninterference provision. To this end, the agency proposes to set forth the parameters of the limits of the agency's involvement in competitive market negotiations leading to the selection of drug products to be covered under Part D formularies. CMS also provides its interpretation of the noninterference provision's requirement that CMS not require "a particular formulary or institute a price structure for the reimbursement of covered Part D drugs."

With regard to negotiations between "between drug manufacturers and pharmacies and PDP sponsors," CMS proposes a specific textual construction of the noninterference provision, arguing that the statute applies to only certain types of negotiations. The agency asserts that the noninterference clause only applies to negotiations either: (1) between drug manufacturers and plan sponsors (or intermediary contracting organizations); or (2) between drug manufacturers and pharmacies. The agency bases its interpretation on "the sequential phrasing of the clause 'negotiations between (among) drug manufacturers and pharmacies and PDP sponsors.'"[3]

> Because in general these negotiations are not among all three parties at once, and because manufacturers separately contract with pharmacies for the purchase of inventory and with sponsors for formulary placement, we believe the quoted phrase can be interpreted as recognizing these distinct types of negotiations. Under such a reading, the prohibition on interference in negotiations, as described in section 1860D-11(i)(1) of the Act, would not pertain to negotiations between Part D sponsors and pharmacies.[4]

While CMS acknowledges some specific statutory limits on its ability to involve itself in Part D sponsors' arrangements with their network pharmacies,[5] the agency views Section 1860D-11(i)(1) as not generally applicable to sponsor-pharmacy negotiations.[6] As additional support for this interpretation, the agency points to congressional intent behind the noninterference clause which it believes supports the view that the provision was enacted to primarily protect manufacturer-sponsor negotiations.[7] CMS also points to the provision's statutory context: "There are numerous statutory provisions that require us to directly intervene in the contractual relationship between Part D sponsors and network pharmacies, and these provisions clearly signal that the Congress expected CMS involvement in at least some of these negotiations."[8] In addition, the agency notes that it has observed a "growth in related-party relationships

[3] 79 FED. REG.1970.

[4] Id.

[5] As an example, the agency will not "intervene in contractual disputes between sponsors and network pharmacies except in matters implicating CMS requirements, because to do so might distort private market outcomes in unpredictable ways." 79 FED. REG.1971.

[6] Id.

[7] "We note that in The Medicare Prescription Drug, Improvement and Modernization Act of 2003 Conference Agreement, in addition to the statutory language, MMA drafters included the following sentence: 'Conferees expect PDPs to negotiate price concessions directly with manufacturers.' We believe this statement supports our understanding that the primary focus of section 1860D-11(i) of the Act is on the negotiations between plans sponsors (or their intermediary contracting organizations) and manufacturers for rebates and other price concessions that ultimately determine which multiple source products will be placed on a sponsor's formulary." 79 FED. REG. 1970.

[8] Id.

between Part D sponsors and network pharmacies, where the distinction between the sponsor and the pharmacy is increasingly unclear,"[9] and so the agency believes Congress would not have intended that the noninterference provision prohibit agency oversight of the sponsor's dealings with itself in such cases.

CMS proposes to codify its new position in a regulation to be added at 42 C.F.R. § 423.10. The new regulation, entitled "Prohibition on intervention in negotiations with manufacturers," states that CMS is prohibited from being a party to negotiations between drug manufacturers and pharmacies, or between drug manufacturers and Part D plan sponsors, and from arbitrating disputes concerning the terms and conditions of agreements between those parties.[10] Implicit in this proposed regulation is CMS's position that the noninterference statutory provision does not limit CMS's authority to promulgate rules that affect negotiations between Part D plan sponsors and pharmacies.

CMS's proposed regulation also addresses the second part of the statutory noninterference provision, section 1860D-11(i)(2), which states that CMS "may not require a particular formulary." Since there are other provisions in the Part D statute that give CMS specific authorities with regard to formularies, CMS proposes to interpret that part of the noninterference provision to mean that CMS cannot determine the specific drug products to be included on Part D sponsor formularies or any tier placement of such products. CMS proposes to codify this interpretation in 42 C.F.R. § 423.10(c). Exceptions to this policy will exist where other provisions of the statute require CMS oversight of formularies, such as requirements that particular types of drug entities be on all formularies, or on preferred tiers, in order to provide non-discriminatory access to drugs necessary to treat conditions in all Medicare beneficiaries, or to address drug classes of clinical concern.[11]

Finally, CMS's proposed regulation addresses the last part of section 1860D-11(i)(2) which states that CMS may not institute "a price structure for the reimbursement of covered Part D drugs." The agency interprets that as prohibiting it from "establishing either absolute or relative indices of prices for Part D drugs." Specifically, CMS proposes that 42 C.F.R. § 423.10(d) specify that CMS does not establish drug product pricing standards or the dollar level of price concessions at any stage in the drug distribution channel for Part D drugs.[12] CMS notes that this prohibition must be interpreted consistently with other provisions of Part D which require the agency to "regulate many aspects of how drug costs are made available and displayed to beneficiaries and treated in Part D bidding and payment processes."[13] To this end, CMS states in proposed section 423.10(d)(2) that nothing in the noninterference provision limits CMS's authority to require full disclosure or uniform treatment and reporting of drug costs and prices under its regulations.

Judicial Review of the Secretary's Interpretation of the Noninterference Provision

If the Secretary's proposed interpretation of the noninterference provision were finalized and challenged as being outside the scope of the Agency's authority under the Administrative Procedure Act,[14] a

[9] Id. at 1971.

[10] 42 C.F.R. § 423.10(b).

[11] *See* Section III.A.14 of the Proposed Rule at 79 FED. REG. 1936.

[12] 79 FED. REG. 1972.

[13] Id.

[14] The Administrative Procedure Act (APA) provides standards of judicial review that a court will use to determine whether an (continued...)

determination of whether the Agency exceeded its delegated authority in issuing the noninterference regulation under Medicare Part D may hinge on the degree of deference that a reviewing court would accord CMS's reading of the statute.[15] Courts have traditionally "recognized that considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer."[16] While it may be likely that a reviewing court would find that CMS has the authority under the Part D statute to provide "a clear, formal interpretation of [the noninterference provision's] limits" on its authority, it may be possible that the courts might not defer to CMS's specific reading of the provision's requirement that the agency not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors.

Judicial Standard for Review of Administrative Interpretations

The current standard for judicial review of an agency's statutory interpretation was originally delineated in *Chevron U.S.A. Inc. v. Natural Resources Defense Council.*[17] There, the Supreme Court established that judicial review of an agency's interpretation of a statute through a formal agency process[18] consists of two steps. First, the court must determine whether Congress has spoken directly to the precise issue at hand. If the intent of Congress is clear, the inquiry is concluded, since the unambiguously expressed intent of Congress must be respected, and the "law must be given effect." [19] However, if the court determines that the statute is silent or ambiguous with respect to the specific issue at hand, the court proceeds to the second step to determine whether the agency's interpretation is based on a permissible construction of the statute. If so, the court will generally defer to the agency's position,[20] although there have been cases in which the Court has found that the agency's interpretation was unreasonable even though Congress has left the matter for agency resolution.[21]

(...continued)

agency's action is valid. 5 U.S.C. §§ 702, 704. For example, the APA provides that a reviewing court must set aside agency actions that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). The APA also states that a reviewing court must "hold unlawful and set aside agency actions, findings, and conclusions found to be ... in excess of statutory jurisdiction, authority, or limitations, or short of statutory right. 5 U.S.C. § 706(2)(C).

[15] A reviewing court ultimately must determine whether the agency has stayed within the bounds of its statutory authority. City of Arlington v. FCC, 133 S. Ct. 1868 (2013).

[16] Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 844 (1984) *(Chevron)*. For more information on court treatment of agency interpretations under *Chevron*, see CRS Report R43203, *Chevron Deference: Court Treatment of Agency Interpretations of Ambiguous Statutes*, by Daniel T. Shedd and Todd Garvey.

[17] 467 U.S. 837 (1984).

[18] In *United States v. Mead Corporation*, 533 U.S. 218, 229 (2001), the Court held that an agency's implementation of statutory authority "qualifies for *Chevron* deference when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority." *Mead* thus established a threshold requirement (what has been referred to as "step zero") restricting *Chevron* deference to only formal rules and other interpretations holding the "force of law" and promulgated pursuant to delegated authority. Policy statements, agency manuals, and interpretive letters, on the other hand, generally do not warrant such deference. *See also* Christensen v. Harris County, 529 U.S. 576 (2000).

[19] *Chevron*, 467 U.S. at 843. The *Chevron* test, which has been cited and followed thousands of times by federal courts since 1984, requires courts to enforce the clearly expressed intent of Congress. Stephen G. Beyer et al. ADMINISTRATIVE LAW AND REGULATORY POLICY 247 (2006).

[20] *See, e.g.*, Astrue v. Capato, 132 S. Ct. 2021 (2012) (deferring to the Social Security Administration's longstanding interpretation in regulations, finding the regulations "warrant the Court's approbation" as they were "neither arbitrary or capricious in substance, [n]or manifestly contrary to statute" (internal quotations omitted)).

[21] Whitman v. American Trucking Ass'n., Inc., 531 U.S. 457 (2001).

It is important to note that the second step does not require a court to "conclude that the agency construction was the only one it permissibly could have adopted to uphold the construction, or even the reading the court would have reached if the question initially had arisen in a judicial proceeding."[22] The practical effect of this maxim is that a reasonable agency interpretation of an ambiguous statute must be accorded deference, even if the court believes the agency is incorrect.[23] Under *Chevron* then, it is generally left to federal agencies, and not the courts, to resolve ambiguities necessary to interpret and implement authority provided to the agency by Congress.

Chevron Step One

At step one under *Chevron*, a reviewing court must determine "whether Congress has directly spoken to the precise question at issue."[24] If the court, "employing the traditional tools of statutory construction," determines that Congress has directly addressed the issue, then that is the end of the matter, because the "law must be given effect."[25] As the United States Supreme Court stated in *Connecticut National Bank v. Germain*:

> [I]n interpreting a statute a court should always turn first to one cardinal canon before all others. We have stated time and again that courts must presume that a legislature says in a statute what it means and means in a statute what it says there.... When the words of a statute are unambiguous, then, this first canon is also the last: judicial inquiry is complete.[26]

CMS, in its preamble to the new Medicare Part D regulations, asserts that the plain text of section 1860D-11(i)(1) providing that the Secretary "may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors" should be read to mean that the statute applies to only certain types of negotiations, i.e., either between drug manufacturers and plan sponsors or between drug manufacturers and pharmacies. The agency bases its interpretation on "the sequential phrasing of the clause 'negotiations between (among) drug manufacturers and pharmacies and PDP sponsors.'"[27]

It is possible that a court may not agree with CMS's textual argument that the statutory language should be read disjunctively as if the final "and" were really an "or."[28] Since the statute repeatedly uses the conjunctive "and," it may be that Congress was listing the principal players involved in the Medicare Part D market, and did not intend to exclude any combination of relationships among the three named entities to which the noninterference provision applies. In such a case, a court may find that Congress has directly spoken to the issue of the Secretary's interference with negotiations between drug manufacturers, pharmacies and PDP sponsors, and that the Secretary's reading is at variance with the plain language of

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[22] *Chevron*, 467 U.S. at 843, n. 11.

[23] Id. at 845. *See also*, National Cable and Telecommunications Association v. Brand X Internet Services, 545 U.S. 967 (U.S. 2005) (ruling that a federal court under the "Chevron doctrine" is required to defer to an agency's interpretation of law — even if it differs from the court's own views — if the particular statute is within the agency's administrative authority, if it is ambiguous on the point in contention, and if the agency's interpretation is "reasonable").

[24] *Chevron*, 467 U.S. at 842.

[25] Id. at 843.

[26] 503 U.S. 249, 254 (1992) (citations omitted). *See also* Caminetti v. United States, 242 U.S. 470, 485 (1917) ("It is elementary that the meaning of a statute must, in the first instance, be sought in the language in which the act is framed, and if that is plain, and if the law is within the constitutional authority of the law-making body which passed it, the sole function of the courts is to enforce it according to its terms.").

[27] 79 FED. REG. 1970.

[28] *See, e.g.*, Loving v. IRS, No. 13-5061, (D.C. Cir. 2014), slip opinion at 11.

the statute. In other words, a reviewing court may find that Section 1860D-11(i)(1) cannot be read to permit CMS involvement in negotiations between pharmacies and plan sponsors, except as required under other provisions of the Part D program. In such a case, *Chevron* deference would not apply. On the other hand, if a court views the negotiation language of the noninterference provision as sufficiently non-specific to trigger deferential analysis under *Chevron*, it might then proceed to the second step of *Chevron's* two-part analysis.

A reviewing court might also note that it appears CMS is changing its prior position regarding the scope of its limitations under the noninterference provision. CMS's interpretation of the noninterference provision in its proposed new section 42 C.F.R. § 423.10, is, as CMS states, its first formal interpretation of that provision. However, CMS has informally interpreted its authority to interfere in negotiations between pharmacies and plan sponsors differently in the past. In January 2005, when CMS promulgated its initial final rule implementing the Part D program, CMS stated in response to comments in its preamble to the regulations that it interpreted the noninterference provision as extending to negotiations between any of the specified parties, including negotiations between Part D plan sponsors and pharmacies. CMS stated: "As provided in section 1860D-11(i) of the Act, we have no authority to interfere with the negotiations between Part D plans and pharmacies and therefore cannot mandate that Part D plans negotiate the same, or similar, reimbursement rates with all pharmacies."[29] Thus, the current Proposed Rule reflects a different perspective on the administration of drug benefits under the Part D program in comparison with the Agency's position nine years ago.[30] An agency clearly has the authority to change or revise a prior interpretation of a statute it administers; nevertheless a new or refined interpretation must be found to be consistent with the legislative language and Congress' intent.[31]

The Proposed Rule also defines the scope of the noninterference provision's directive that CMS may not require a particular formulary or institute a price structure for Part D covered drug reimbursements. Specifically, in proposed new 42 C.F.R. § 423.10(c) and (d), CMS states that it does not determine the specific drug products to be included on Part D sponsor formularies or any tier placement of such products, and does not establish specific drug product pricing standards or the dollar amount of price concessions at any stage in the drug distribution channel for Part D drugs. With regard to CMS's interpretation of its formulary and price structure restrictions, a court is more likely to find that Congress has provided a "delegation of authority to the agency to elucidate [the] specific provision of the statute by regulation."[32] The agency's interpretation, therefore, would likely receive judicial deference under the second part of the *Chevron* test.

Chevron Step Two

As noted above, under the second step of *Chevron*, if Congress has not directly spoken to the question at issue, the reviewing court's role is limited to determining whether the agency's interpretation was "based on a permissible construction of the statute."[33] Where Congress has not clearly expressed its intent, a

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[29] 70 FED. REG. 4194-4585 (January 28, 2005) at 4255, available at http://www.cms.gov/Regulations-and-Guidance/Regulations-and-Policies/QuarterlyProviderUpdates/downloads/CMS4068F.PDF.

[30] This view includes a changed view of the relationships between Part D plan sponsors and pharmacies, preferred pharmacies, mail-order pharmacies and other aspects of Part D benefit plan administration.

[31] *See* FCC v. Fox Television Stations, Inc., 556 U.S. 502, 515 (2009). When an agency changes its position on a matter within its authority to implement a statute, the courts generally require that the agency "display awareness that it is changing its position" and show that "there are good reasons for the new policy."

[32] *Chevron*, 467 U.S. at 843-44.

[33] Id. at 842-43. *See* Thomas J. Miles and Cass R Sunstein, *Do Judges Make Regulatory Policy? An Empirical Investigation of* (continued...)

court "may not substitute its own construction of a statutory provision for a reasonable interpretation" of the agency.[34] The Supreme Court has indicated that deference to an agency's interpretation under step two is appropriate "whether or not it is the only possible interpretation or even one a court might think best."[35] Thus, if a reviewing court determines that there is ambiguity as to whether the noninterference provision applies to negotiations between pharmacies and plan sponsors, and so reaches step two of the *Chevron* analysis with respect to the agency's interpretation, the court may, depending upon the record presented, consider the agency's interpretation to be a permissible construction of the statutory text, and, as such, to be accorded deference by the court.

Conclusion

In January 2014, CMS proposed significant changes in the way it administers several aspects of the Medicare Part D program. The proposed rule includes the agency's formal interpretation of Section 1860D-11(i) of the Social Security Act, the noninterference provision. This provision generally prohibits the Secretary from interfering with negotiations between drug manufacturers and pharmacies and PDP sponsors, and prevents CMS from requiring that plans have a particular formulary or instituting a price structure for the reimbursement of Part D covered drugs. The purpose of this provision is "to promote competition under [Part D]."[36]

CMS proposes to change its position regarding the scope of negotiation limitations of the noninterference provision, and to codify its interpretation of that provision in a new regulation at 42 C.F.R. § 423.10. CMS, in its preamble to the new Medicare Part D regulations, asserts that the plain text of section 1860D-11(i)(1), which provides that the Secretary "may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors," should be read to mean that the statute applies to only certain types of negotiations, i.e., either between drug manufacturers and plan sponsors or between drug manufacturers and pharmacies, but not negotiations between PDP sponsors and pharmacies. The agency bases its interpretation on "the sequential phrasing of the clause 'negotiations between (among) drug manufacturers and pharmacies and PDP sponsors,'"[37] as well as on congressional intent and the context of the noninterference provision within the Part D statute. The new regulation would also define the scope of the noninterference provision's prohibition against requiring a formulary or instituting price structures for covered Part D drugs.

Under the Supreme Court's landmark and oft-cited decision in *Chevron U.S.A. Inc. v. Natural Resources Defense Council*,[38] judicial review of an agency's interpretation of a statute through a formal rulemaking process consists of two steps. First, the court must determine whether Congress has spoken directly to the precise issue at hand. If the intent of Congress is clear, the inquiry is concluded, since the unambiguously expressed intent of Congress must be respected, and the "law must be given effect."[39] However, if the court determines that the statute is silent or ambiguous with respect to the specific issue at hand, the court

(...continued)

Chevron, 73 U. Chi. L. Rev. 823 (2006) (finding that more than 90 percent of invalidations under Chevron occurred at Step One).

[34] Id. at 844.

[35] *See, e.g.*, Holder v. Gutierrez, 132 S. Ct. 2011 (2012), *citing Chevron*, 467 U.S. at 843-44.

[36] Section 1860D-11(i).

[37] 79 FED. REG. 1970.

[38] 467 U.S. 837 (1984).

[39] Id. at 843.

proceeds to the second step to determine whether the agency's interpretation is based on a permissible construction of the statute.

If the Secretary's proposed interpretation of the noninterference provision were finalized and challenged as being outside the scope of the Agency's authority under the Administrative Procedure Act, it is possible that a reviewing court might not be persuaded by the Secretary's textual argument that the noninterference provision does not clearly apply to negotiations between PDP plan sponsors and pharmacies. A court might conclude that Congress has directly spoken to the issue of the Secretary's interference with negotiations between drug manufacturers, pharmacies and PDP sponsors, and that the Secretary's reading is at variance with the plain language of the statute. In such a case, *Chevron* deference would not apply. On the other hand, if a court views the negotiation language of the noninterference provision as sufficiently non-specific to trigger deferential analysis under *Chevron*, it might then proceed to the second step of *Chevron's* two-part analysis, and possibly consider the agency's interpretation to be a permissible construction of the statutory text, and, as such, to be accorded deference by the court.

Mr. GINGREY. Let me just conclude. I am urging you, Mr. Blum, to withdraw this rule, and I personally, as a member of this committee, am prepared, and I will also urge our leadership, fight with every tool available to repeal this rule legislatively if you guys do not heed the wishes of our seniors and the American people.

I have gone over my time, and, of course, I yield back, Mr. Chairman.

Mr. PITTS. Chair thanks the gentleman. And I would like to ask the staff to provide a copy to the minority, please.

Chair now recognizes the gentleman from Florida, Mr. Bilirakis, 5 minutes for questions.

Mr. BILIRAKIS. Thank you, Mr. Chairman. I appreciate it very much.

And again, I represent over 100,000 seniors in the Tampa Bay area, and they seem to be very pleased with Medicare Part D, and I am along with Dr. Gingrey: If it ain't broke, don't fix it.

Mr. Blum, specifically, I am concerned about CMS' reinterpretation of the noninterference clause of the Medicare Part D statute. It was clearly written so that CMS would not interfere with the negotiations between drug manufacturers, pharmacies, and Part D sponsors.

You may or may not know that I am in a unique position here, since my father, Congressman Mike Bilirakis, was the chairman of the subcommittee, and again, he remembers the intent of the law as written by him and his colleagues, and it was not to allow CMS to interfere in any of these negotiations. And I was in the legislature at the time in 2003, and I followed this as well, and that was my interpretation of the law, that the intent was for CMS not to interfere, and not to allow CMS to interfere again in the negotiations.

You should know that, of course, you were the—I believe you were on Senator Baucus' staff at that time, so I am sure you remember. So I would like to ask you, Mr. Blum, are you telling me that the authors of the legislation, of course, including my father, are wrong when they say that they intended for CMS not to interfere in these negotiations?

Mr. BLUM. So going back to my days on the Senate Finance Committee, I worked with your father and his staff during the conference committee that produced the final Part D legislation, and so I understand well the intent of the Congress at the time. Senator Baucus, my former boss, and the team that he had, myself included, were directly involved in the drafting of the Part D legislation. So I understand well why Congress chose to put in place the noninterference clause.

While we understand the disagreement, and it is clear from this hearing today there is a disagreement, we proposed the change with the interest to make the provision work better, to have it be stronger, to make it really clear when CMS will and won't get involved with contract disputes—with Part D sponsors and pharmacies. We get asked frequently to get involved with those disputes, and we want to kind of articulate to the public when and won't CMS try and broker, you know, beneficiary access issues or pharmacy network issues.

Mr. BILIRAKIS. OK.

Mr. BLUM. We will thoroughly review—I look forward to looking to the CRS documents to understand our authority to make sure that our legal team understands it, but as I said several times during this hearing, our intention is not to interfere with the price——

Mr. BILIRAKIS. Thank you.

Mr. BLUM [continuing]. Negotiations.

Mr. BILIRAKIS. And you understood the intent of the law then, and now you understand it as well.

Mr. BLUM. Having served on the Finance Committee staff during the 2003 drafting, I understand the 2003 legislation——

Mr. BILIRAKIS. Thank you.

Mr. BLUM [continuing]. Well.

Mr. BILIRAKIS. Thank you, sir, because I don't have a lot of time, I want to get onto the next question. Appreciate it.

You justify some of the changes in the rule as a means to address prescription drug abuse. It seems to me that we could manage some of the prescription drug problem through the use of a pharmacy lock, the lock-in program, where a single point of sale could provide more protection against the problem of doctor shopping, pharmacy shopping, and inappropriate drug therapies for high-risk beneficiaries. Pharmacy lock-in has been used successfully in State Medicaid, of course, as you know, and also with TRICARE and commercial insurance. Are you in support of pharmacy lock-in, sir?

Mr. BLUM. I testified on the record last summer to the Senate Homeland Security Committee that we believe lock-in provisions can help to reduce inappropriate prescribing, prescriber fraud. We have concluded that Congress would have to act to authorize us to allow pharmacy lock-in, but we believe that is a change that Congress should make.

Mr. BILIRAKIS. So in other words, you agree with the pharmacy lock-in. Why isn't it in this particular rule?

Mr. BLUM. We don't have the authority for that change. I testified that Congress would have to give us that authority.

Mr. BILIRAKIS. OK. I have introduced a bipartisan bill on this particular issue, but staff at CMS have not replied to requests from this committee for technical assistance on this bill. Today, would you commit to me, you personally, to review this legislation that I have offered? I have actually filed it. It has been about a couple——

Mr. BLUM. Absolutely.

Mr. BILIRAKIS [continuing]. A few months. So I would like to get your feedback——

Mr. BLUM. Yes.

Mr. BILIRAKIS [continuing]. With regard to this legislation. Would you personally commit to me that you will review that and respond to me?

Mr. BLUM. Absolutely.

Mr. BILIRAKIS. OK, thank you very much. Appreciate that.

Mr. PITTS. Chair thanks the gentleman. Chair thanks Mr. Blum for spending 2½ hours with the subcommittee this morning. We really appreciate your time and patience. We will send you additional questions. We ask that you please respond to those promptly.

There are two things I want to highlight. Dr. Burgess' question was for the full and complete cost analysis that led to the rule. If you will provide that. And Mr. Guthrie's question, the call sheets, the full complaint data that you referenced that you say shows seniors don't like their Part D plans, would you provide those to the committee?

Mr. BLUM. To clarify the complaint data, in 2013 CMS received over 30,000 complaints on various Part D issues. We have to protect beneficiary confidentiality, but we will do our best to make sure that we can summarize that data in a way that would be helpful to this committee.

Mr. BURGESS. Redact the names and let us have it.

Mr. PITTS. Go ahead.

Mr. BURGESS. Mr. Chairman, I think you can redact the names and let us have the information.

Mr. BLUM. We will look into it.

Mr. BURGESS. The complaints themselves will be significant.

Mr. BLUM. Yes, we will look into it, sir.

Mr. BURGESS. Thank you, Mr. Chairman.

Mr. PITTS. All right. Chair thanks the gentleman. We will now take a 5-minute recess as the second panel sets up.

[Recess.]

Mr. PITTS. Our time of recess having expired, we will go to our second panel. We have three witnesses on our second panel today. We have Mr. Douglas Holtz-Eakin, President, the American Action Forum; Mr. Carl Schmid, Deputy Executive Director, The AIDS Institute; Mr. Joe Baker, President of the Medicare Rights Center. Thank you all for coming. You will each have 5 minutes to summarize your testimony. Your written testimony will be placed in the record.

Dr. Eakin, you are recognized for 5 minutes for your opening statement.

STATEMENTS OF DOUGLAS HOLTZ–EAKIN, PRESIDENT, AMERICAN ACTION FORUM; CARL SCHMID, DEPUTY EXECUTIVE DIRECTOR, THE AIDS INSTITUTE; AND JOE BAKER, PRESIDENT, MEDICARE RIGHTS CENTER

STATEMENT OF DOUGLAS HOLTZ—EAKIN

Mr. HOLTZ-EAKIN. Well, thank you, Chairman Pitts, and Ranking Member Pallone, members of the committee, for the privilege of being here today to discuss what I consider to be a crucial proposed rule from CMS.

You have my written statement. Let me make just a few brief points at the outset. First, as has been discussed, the Part D Program has a tremendous record of success. It has come in well below the projected budget costs, and I note with irony that Mr. Blum said one reason to do this rule is CBO was saying it is going to cost so much in the future, when it came in at $55 billion, after my CBO projected it would cost $122 in 2012.

It also has had stable beneficiary premiums, it has a very high level of beneficiary satisfaction, 85 percent of seniors are very happy with Part D. For those who are interested in the statistics on this, I will point out 30,000 complaints is less than 1/10 of a per-

cent of Medicare beneficiaries. So we have approval at 85, complaints at under 1/10 of 1 percent. And seniors have, in 2013, at least 23 choices in every plan area. And so that record of success is not an accident. If you think about how Part D works, the plans sit in the middle and the plan sponsors, and they negotiate with the drug manufacturers discounts on their drugs on the basis of a volume of business they can deliver. And to do that, over here they go out and offer different plans with different formularies, not to confuse seniors but to attract more volume and get better deals over here, and they develop these preferred pharmacy networks with special provisions, again, by offering lower prices, they get more volume, they get more ability to negotiate over here with the drug manufacturers. That capacity to undertake these negotiations is at the heart of the success of Part D. And for Mr. Blum to suggest that by setting a saving standard—a minimum saving standard, that you have to get in a preferred pharmacy network, that is a direct intervention in the price negotiation for those pharmacies, and to suggest that you offer to someone you have never negotiated with exactly the same deal you have given to somebody you have negotiated with, that is a direct intervention of the negotiations. I believe that the idea that this is not violating Congressional intent with the noninterference clause is just transparently false. I mean I was there at the birth of the Part D benefit, as were many in this committee. This is just flatly inconsistent with what Congress intended.

I am not a lawyer, so I don't know about the statutory authority, but the lawyers I have consulted with say they don't have the authority to do this. And for Mr. Blum to suggest that it somehow strengthens the noninterference clause is just Orwellian doublespeak, and I am deeply troubled by the fact that they would do this.

The implications, I think, are very important. First, and this is your self-interest, if they do this in Part D, they don't need you anymore. Not this committee, not the full committee, not the House, not the Senate, not the Congress. They can do whatever they want with the Part D benefit, and I believe that is an inappropriate power for an administration to have. And it would also hurt the program as a whole because if you are a plan sponsor, and you have an administration that has the power to do whatever it wants without real consideration of the consequences, you are either not going to participate or you are going to charge a lot to participate, and that is going to hurt the seniors, which, in the end, are the focal point of the program.

So I believe those provisions are ones that certainly cannot be rushed through in the next couple of weeks. It shouldn't happen at all, and I would urge the committee to do everything in their power to stop them.

The other features of the rule, there are many details in here, but limiting the number of plans qualms the negotiations that they can do with the drug manufacturers. As a result, there is no real way that CMS can claim to be monitoring savings in the program by looking at one half of this equation. That is incomplete and incorrect, and any support for this rule on that basis has to be questioned. They need to provide a lot better support, as in the cost

analysis that you mentioned. I think that overall there have been some private estimates to suggest the limiting in choice, the limiting competition is going to raise plan bids by about 10 percent. That may not directly translate into 10 percent higher premiums for beneficiaries, but those 10 percent costs will go somewhere in the system. That is bad news for taxpayers, bad news for beneficiaries, or both, and we need to be concerned about that.

There is no question that I think this leads to higher budget costs for a program that has consistently surprised on the downside, and, you know, we have had a lot of discussion, this is going to restrict some seniors' access to their doctors and/or their particular pharmaceuticals, and those are steps in the wrong direction from the point of view of the program.

I guess the last thing I would close with is there has been a lot of discussion about seniors getting in the right plan. It is not as if there is no other way to do that. This is a terrible way to solve that problem. Mr. Blum runs a Web site called Medicare.gov, with a plan finder. He might want to devote his efforts to improving that.

Thank you.

[The prepared statement of Mr. Holtz-Eakin follows:]

Damaging Medicare Part D:
CMS Proposes Unnecessary Changes to a Successful Program

U.S. House of Representatives
Energy and Commerce Committee
Subcommittee on Health

Douglas Holtz-Eakin, President*
American Action Forum

February 26, 2014

*The views expressed here are my own and not those of either the American Action Forum or the Partnership for the Future of Medicare. I thank Angela Boothe, Emily Egan, and Christopher Holt for their assistance.

Chairman Pitts, Ranking Member Pallone, and members of the Committee, thank you for the opportunity to share my thoughts on the Part D program and the administration's proposed changes. In what follows, I hope to convey the following major points:

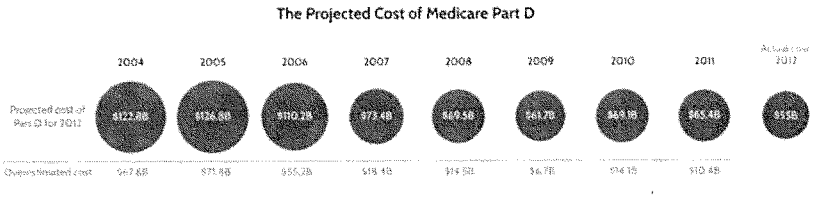
1. The Medicare Part D program is a proven success story of bipartisan Medicare reform, making affordable prescription drug coverage available to seniors and the disabled;
2. The proposed new rule entitled "Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs" clearly violates the intent of Congress when it passed the Medicare Modernization Act (MMA) and rests on a questionable legal foundation by interfering with the established negotiation processes;
3. Policy analyses show that the proposed rule is likely to raise costs for seniors, programs, and the federal taxpayers, unnecessarily harming the superb record that the competition-based design of Part D has built; and
4. The rule imposes requirements that will decrease seniors' access to vital prescription drugs.

Choice, Competition, and the Success of Part D

Since its enactment, the Part D program has continually proven its ability to control beneficiary and budget costs, provide consistently high quality drug plans and exemplify market-based competition within an entitlement program. Established as part of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA), Part D was designed to increase seniors' access to outpatient prescription drugs through the Medicare program. The goal of the policymakers who developed Part D was to provide a stable mechanism for competing insurance issuers to offer prescription drugs at negotiated prices to Medicare beneficiaries.[1] In the past ten years, the program has more than achieved its goals: costing taxpayers much less than the original budgetary projections, providing a wide variety of low cost plan options, and maintaining member satisfaction.[2]

The Medicare Part D program has consistently performed under budget, coming in at a cost of $55 billion in 2012 – that is down from an estimated 2012 cost of $122.88 billion as predicted in 2004[3] (see Graphic 1). Much of the observed savings come from the program's competitive design, unhampered negotiations and consumer choice, serving as the backbone policies of the Part D program. Unlike many government programs, plan issuers have the flexibility to develop a wide range of products and as long as a benchmark standard is met, tiered cost-sharing, additional benefits, and savings from using a preferred network of pharmacies can all be utilized to appeal to consumers.

Graphic 1: Decrease in Projected 2012 Costs of Medicare Part D



The annual Part D bidding process allows issuers to place bids for plans in any or all of the thirty four regions in the country. These issuers submit a bid displaying the potential per member per month (PMPM) cost of providing benefits to members in any (or all) of the established regions. All bids contain a rate for the basic benefit or "standard plan" as well as an enhanced benefit plan that goes above and beyond the minimum plan requirements. Part D members can choose whether they would like to participate in a plan that contracts with nearby pharmacies as part of a preferred pharmacy network (PPN), pay a higher premium for plans with enhanced benefits, or save money by selecting a standard plan.

Despite initial worries about plan participation, this process of bidding and selection has led to a large number of available plans, giving seniors in every region at least 23 plan choices in 2013.[4] The open competition for beneficiaries has resulted in a robust market. The ability for plan issuers to negotiate with preferred pharmacy networks, pharmaceutical companies and pharmacy benefit managers has allowed plans to utilize their market share to obtain lower prices and thus charge lower premiums. For example, a plan may offer drug A at a lower copayment than an equivalent drug B, and in exchange for doing so they negotiate rebates from the manufacturer of drug A. As a result, patients who have a condition that warrants drug A or B are able to obtain A at a lower out of pocket cost, and the Part D plan receives the rebate for every purchase, and thus allows them to price their plan more affordably.

The success of the program is not an accident; Part D is designed to provide seniors with affordable choices. Competitive bidding and plan selection have led to high-quality products, as measured through member satisfaction rates. Despite initial concerns about plan enrollment and member participation, 31 million[5] individuals were enrolled in the Part D program in 2012, with 85 percent reporting that they are "satisfied" with their coverage and nearly 80 percent of members felt that they made a "good choice" with their coverage option.[6] The satisfaction reported by seniors displays the use of an efficient, high quality program that continues to come in under cost projections and maintain popularity among its members.

Proposed Regulations and the Future Success of Part D

The proposed rule posted by CMS on January 10, 2014, would alter the program operations, jeopardizing Part D's success and quality. The CMS initiative may increase premiums and co-payments, disrupt continuity of care and impact access for Part D beneficiaries. If implemented, the rule will drive up costs by interfering with the ability of plans to negotiate prices, decrease access to services and reduce the number of existing plans.

Violating Statutory Non-Interference. The Part D statute contains a non-interference provision that prohibits the Secretary of Health and Human Services (HHS) from interfering with the negotiations between drug manufacturers and pharmacies and sponsors of prescription drug plans, and from requiring a specific price structure for Part D reimbursement.[7] The clear Congressional intent of the noninterference provision was to allow for free negotiations between drug manufacturers and pharmacies and plan sponsors. This is exemplified by the letter I signed as Director of the Congressional Budget Office immediately after the passage of MMA.[8]

As the letter makes clear, plans, manufacturers and pharmacies were all covered by the non-interference provision. CMS has changed the agency's interpretation of the law to permit CMS intervention in pharmacy and plan sponsor negotiations. I believe this is a clear violation of Congressional intent.

It is also bad policy. CBO noted at the time of the law's enactment that the involvement of the HHS Secretary in price negotiations will not create any additional benefits during the negotiation process.[9] Plans have enough leverage with their high number of potential beneficiaries to negotiate effectively, and the Secretary would not be able to significantly reduce prices. The Secretary cannot improve the current state of the price negotiation process, and federal price fixing would prove detrimental to the current competitive price negotiations.

Finally, its legal foundation is questionable as legal experts find this rule to directly conflict with previous HHS interpretations of the MMA. According to a legal opinion produced by the firm Boyden Gray and Associates, PLLC, the legislative history, previous regulatory interpretations and subsequent repeal proposals all point to the clarity of the "non-interference provision".[10] As the opinion states, the non-interference provision was particularly controversial during the legislative debate as all policymakers understood that it barred HHS from inserting itself in pharmaceutical negotiations as they occurred between plan sponsors, drug manufacturers and pharmacies.[11] As it exists today these contracts are negotiated freely and in line with the established understanding of strict non-interference. Should HHS choose to ignore the "undisputed understanding" of this law, the regulatory overreach sets a disconcerting precedent for further administrative intrusion. If the agency moves forward with its novel interpretation of noninterference, then this overreach should be vacated by the federal courts.

Placing PPNs at Risk. The proposed rule works to undercut the established preferred pharmacy network (PPN) plans. As proposed in the regulation, the "any willing pharmacy" requirement forces plans to accept any pharmacy that is willing to meet the terms of their contract.[12] These preferred networks are not intended to be exclusionary, but instead are agreements between specific pharmacies in order to ensure a members-only discount. This requirement could cause millions of seniors to lose their plans that provide discounted prices through a preferred

pharmacy network, a part of the program that is projected to save $9.3 billion over the next ten years.[13]

Placing the Taxpayer at Risk. The loss of preferred pharmacy networks will increase costs for Part D through the removal of discounted membership rates, interfere with seniors' continuity of care, and decrease the quality of coverage. Seniors losing their current, preferred pharmacy network (PPN) plan would no longer experience the savings associated with these networks. In 2014, the average premium for a basic PDP within a preferred network was 21 percent lower than the average premium for non-preferred network plans.[14] Table 1 displays the number of enrollees in every state that stand to lose their Part D prescription drug coverage and could experience premium increases in 2015 if the CMS proposal is implemented.

Budget estimates produced by the actuarial firm Milliman show that the regulation, if implemented, will raise program costs up to $1.6 billion for the federal government in 2015 alone, increase plan bids by 10 percent, and drive up enrollee cost-sharing, tarnishing the Part D track record of competitive pricing.[15] According to their study, the proposed regulation would increase the out of pocket costs for 6.9 million seniors that do not qualify for low-income subsidies and would increase federal costs for roughly 6 million low-income beneficiaries.[16] Due to the program design, an increase in the plan bids would be borne by both the Medicare beneficiary as well as the federal government.

Restricting Mail Order Pharmacies. Many preferred pharmacy networks create a portion of the savings described above by utilizing or owning a mail order pharmacy. Mail order pharmacies ship prescriptions directly to Part D enrollees, providing an efficient supply chain and eliminating costs associated with brick and mortar pharmacies. According to CMS itself, pharmaceuticals ordered through mail order pharmacies are estimated to cost 16 percent less on average than retail pharmacies.[17] In addition to the cost savings, having prescriptions delivered by mail is often more convenient for patients and as a result may increase medication adherence. A study performed by Kaiser Permanente found that among diabetes patients, those receiving their medication via mail order pharmacy had fewer emergency department visits.[18]

CMS' proposal includes new requirements for mail order pharmacies that establish a mandated date of shipment and causes complexities with existing beneficiary outreach requirements. In the proposed regulation, CMS requires mail order pharmacies to ship prescriptions within three or five days. Prescriptions that do not have any issues or discrepancies must be shipped within three days and prescriptions that are unclear or require a prior authorization must be shipped within five days. This provision directly conflicts with the requirement of mail order pharmacies to receive patient approval prior to shipment of medications, which can interfere with the proposed time limits. These new requirements add another layer of complexity to the mail order process and impose regulations that do not regard patient/prescription specific circumstances.

Creating Issuer Limitations. Part D enrollees would experience a decrease in the number of available plans along with their increased premiums if the proposed rule is implemented. The intricate negotiations between Part D plan issuers and provider pharmacies have resulted in 1,169 plans in 2014,[19] offering a variety of premium levels and benefits. However, the proposed rule would limit the number of plans per issuer that can be offered in each of the 34 Part D regions in 2016. All issuers would be limited to offering two plans per region: one plan that provides the

standard benefit package and a plan that provides enhanced benefits.[20] According to a study conducted by Avalere, the rule would cause issuers to roll enhanced plans with richer benefits into less generous plans, increasing premiums for existing plans and decreasing the variety of benefits offered.[21] This proposal will greatly impact those enrolled in enhanced benefit plans; the termination and consolidation of enhanced plans may disrupt the Part D benefits for 7.4 million, or 94 percent of individuals enrolled in enhanced plans.[22] According to Milliman, the reduced plan offerings would result in 50 percent of Part D enrollees seeing their plans cancelled or "materially changed."[23]

This provision is the result of concern that seniors have "too many" choices of Part D plans, and can get confused. It is not a result of concern that some of these choices are poor or inadequate. There is likely some truth to the fact that it may take some research for a Medicare beneficiary to figure out which plans provide the best (and least expensive) coverage for the medications they use, but there are plenty of resources to help individuals make these choices. Interfering in a well-functioning market system simply to reduce choices—not to eliminate poor choices, is not good policy.

Conclusion

The proposed rule damages the policy foundations of the Medicare Part D program, creating major changes to the program's operations. CMS should not be able to radically rework a successful program that impacts so many individuals on a whim. A group of 200 stakeholders and industry leaders have publicly stated their resistance to these changes, showing a broad support for the current status of the program. I am urging Congress not to allow for the finalization of this unneeded rule.

The interpretation of the noninterference provision, changes to preferred pharmacy negotiations, and placing absolute requirements on portions of the program will increase costs, impede the effectiveness, and create dissatisfaction among plan enrollees. Federal involvement will only hinder negotiating practices and increase costs. Allowing any willing pharmacy to participate in preferred networks will increase premiums for enrollees, many of which are seniors on a fixed income. Creating mandates on turnaround times for mail order pharmacies and the number of plans offered in a region blindly restricts mechanisms in the program that create savings. Limiting issuers to offering only two plans per region will increase plan costs, and requiring mail order pharmacies to adhere to specific timelines show a disregard for consumer choice and access. Through this testimony, I am encouraging the roll-back of an unnecessary rule that inhibits a competitively driven, financially successful, popular program.

Table 1: Medicare Beneficiaries in Preferred Network Plans by State				
State	**Medicare Beneficiaries in Preferred Network Plans**		**State**	**Medicare Beneficiaries in Preferred Network Plans**
Alabama	249,530		Montana	56,988
Alaska	21,006		Nebraska	112,141
Arizona	233,826		Nevada	102,284
Arkansas	174,711		New Hampshire	102,747
California	1,200,074		New Jersey	446,486
Colorado	181,349		New Mexico	71,173
Connecticut	170,142		New York	659,179
Delaware	68,294		North Carolina	572,525
District of Columbia	27,004		North Dakota	41,265
Florida	1,007,077		Ohio	490,416
Georgia	425,401		Oklahoma	198,138
Hawaii	17,431		Oregon	124,151
Idaho	61,975		Pennsylvania	515,000
Illinois	76,1137		Rhode Island	50,690
Indiana	401,452		South Carolina	270,856
Iowa	177,282		South Dakota	56,795
Kansas	211,465		Tennessee	328,983
Kentucky	297,432		Texas	946,557
Louisiana	167,474		Utah	58,482
Maine	132,415		Vermont	50,528
Maryland	285,479		Virginia	412,826
Massachusetts	342,840		Washington	240,145
Michigan	537,086		West Virginia	115,704
Minnesota	172,809		Wisconsin	231,236
Mississippi	209,577		Wyoming	36,342
Missouri	330,673			

[1] Medicare Improvement and Modernization Act of 2003. Section 101 (a)(1)(A).
[2] Book, Robert A. Ph.D., Holtz-Eakin, Douglas, Ph.D., Competition in the Medicare Part D Program. September 2013.
[3] Book, Robert A. Ph.D., Holtz-Eakin, Douglas, Ph.D., Competition in the Medicare Part D Program. September 2013.
[4] Andrew Stocking, "Competition and Bids in Medicare's Prescription Drug Program," Congressional Budget Office, June 23, 2013, p.8-9
[5] 2013 Statistical Supplement." *Center for Medicare and Medicaid Services*. Chapter 14: Medicare Part D, Web. <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareMedicaidStatSupp/2013.html>.
[6] Report on Access, Satisfaction, and Cost," AARP, November 2007. http://assets.aarp.org/rgcenter/health/rx_medicared.pdf
[7] The Medicare Improvement and Modernization Act of 2003, 33 § 1860-D (2003). http://www.gpo.gov/fdsys/pkg/BILLS-108hr1enr/pdf/BILLS-108hr1enr.pdf
[8] CBO Letter to Congress. 2004. http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/49xx/doc4986/fristletter.pdf
[9] CBO Letter to Congress. 2004. http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/49xx/doc4986/fristletter.pdf
[10]Boyden Gray and Associates, PLLC. "The Medicare Modernization Act's Prohibition Against Federal Negotiation of Drug Prices." February 24, 2014. http://americanactionforum.org/insights/legal-analysis-of-proposed-part-d-rule-finds-hhs-acting-unlawfully
[11] Boyden Gray and Associates, PLLC. "The Medicare Modernization Act's Prohibition Against Federal Negotiation of Drug Prices." February 24, 2014. http://americanactionforum.org/insights/legal-analysis-of-proposed-part-d-rule-finds-hhs-acting-unlawfully
[12] 79 FR 1978. Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, CMS-4159-P § 3 ,2014. https://www.federalregister.gov/articles/2014/01/10/2013-31497/medicare-program-contract-year-2015-policy-and-technical-changes-to-the-medicare-advantage-and-the#p-790.
[13] Kaczmarek, Stephen J., Andrea Sheldon, and David M. Liner. "The Impact OfPreferred Pharmacy Networks on Federal Medicare Part D Costs, 2014-2023." Milliman, Oct. 2013. Web.
[14] Based on 2014 enrollment in Medicare Part D prescription drug plans with preferred pharmacy networks as reported by the Drug Channels Institute. http://www.drugchannels.net/2014/01/for-2014-3-out-of-4-seniors-choose.html, and "2014 Premiums and Star Ratings for Medicare Part D
Prescription Drug Plans with Preferred Pharmacy Networks" Avalere Health. 2014.
[15] Kaczmarek, Stephen J., and David M. Liner. "Survey Analysis of CMS January 2014 Proposed Rule." Milliman, Feb. 2014.
[16] Kaczmarek, Stephen J., and David M. Liner. "Survey Analysis of CMS January 2014 Proposed Rule." Milliman, Feb. 2014.
[17] Centers for Medicare and Medicaid Services, "Part D Claims Analysis: Negotiated Pricing Between General Mail Order and Retail Pharmacies," December, 2013.
[18] CPatients with Diabetes who use Mail Order Pharmacy are Less Likely to Visit Emergency Rooms." Kaiser Permanente. November 2013. http://share.kaiserpermanente.org/article/patients-with-diabetes-who-use-mail-order-pharmacy-are-less-likely-to-visit-emergency-rooms/.
[19] Hoadley, Jack, Juliette Cubanski, and Laura Summer. "Medicare Part D: A First Look at Plan Offerings in 2014 « » The Henry J. Kaiser Family Foundation." *Kaiser Family Foundation*. N.p., Oct. 2013. Web. <http://kff.org/medicare/issue-brief/medicare-part-d-a-first-look-at-plan-offerings-in-2014/>.
[20] 79 FR 1963. Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, CMS-4159-P § 3 (2014. https://www.federalregister.gov/articles/2014/01/10/2013-31497/medicare-program-contract-year-2015-policy-and-technical-changes-to-the-medicare-advantage-and-the#p-689.
[21] Eyles, Matthew. "7.4 Million Beneficiaries Could Be Affected by Proposed Meaningful Differences Policy." *Avalere Health*. N.p., Feb. 2014. Web. <http://avalerehealth.net/expertise/managed-care/insights/7.4m-medicare-beneficiaries-could-be-affected-by-proposed-meaningful-differ>.

[22] Eyles, Matthew. "7.4 Million Beneficiaries Could Be Affected by Proposed Meaningful Differences Policy." *Avalere Health.* N.p., Feb. 2014. Web. <http://avalerehealth.net/expertise/managed-care/insights/7.4m-medicare-beneficiaries-could-be-affected-by-proposed-meaningful-differ>.
[23] Kaczmarek, Stephen J., and David M. Liner. "Survey Analysis of CMS January 2014 Proposed Rule." Milliman, Feb. 2014.

Mr. PITTS. Chair thanks the gentleman. Now recognizes Mr. Schmid for 5 minutes for an opening statement.

STATEMENT OF CARL SCHMID

Mr. SCHMID. Thank you. Good afternoon.

The AIDS Institute is pleased to offer our views on CMS' proposed Medicare Part D rule. Since we believe aspects of the proposed rule would erode a patient's ability to obtain the medications that their providers prescribed, we are urging CMS to scrap the proposal to change the 6 protected classes.

Frankly, just like many of you, we were rather surprised the Obama administration would propose such a rule, given its strong commitment to quality healthcare, including mental health, and to others living with illnesses and diseases.

For people with HIV, and so many other patients, new drug therapies have saved millions of lives, and prolonged millions more. The advent of antiretroviral medications in the late '90's turned HIV from a near certain death to a more manageable disease if patients have access to quality care and medications.

We know all medications are not the same, and each person reacts differently to a particular drug. Doctors and patients together make careful decisions about which therapies are most appropriate on a case-by-case basis. Some individuals may develop side effects to a particular drug, while another may need a therapy to avoid a harmful interaction for a drug being taken for another health condition. For people with HIV, drug resistance can occur, requiring them the ability to switch to another drug without interruption.

It is for these reasons, when Medicare Part D was first implemented, CMS determined that a minimum of only 2 drugs in the class, which is what the law requires, was simply not enough for certain patients, including those with HIV, mental illness, cancer, epilepsy, and those undergoing organ transplantation. The 6 Protected Classes was created so that patients could have access to all the drugs in these classes.

For the past 10 years, Medicare Part D has been working for millions of seniors and people with disabilities, including over 100,000 people a year with HIV. As part of the Affordable Care Act, Congress even codified the 6 protected classes. We see no reason why the protected classes should be changed, and if they were, we would like to see more classes of drugs gain protected status rather than reducing them, so that more patients can gain access to the medications prescribed.

As I commented earlier, we were shocked when we read the proposed rule. The Secretary used the authority granted to her under the ACA to develop criteria to alter the 6 protected classes, and, at the same time, proposed to eliminate 3 of them. One would think if the administration was contemplating any changes, their criteria for class review would be developed first with adequate public comment before it was applied. Instead, a very arbitrary criterion was developed in secret, and then arbitrarily applied at the same time.

Thankfully, the proposed rule continues the protections for antiretrovirals. That would not be the case for antidepressants and

immunosuppressants in 2015, and antipsychotics in 2016, if the proposed law—proposed rule was finalized.

Frankly, we are worried. Who will be next? How much longer will people with HIV, cancer and epilepsy have access to all the medications they need through Medicare Part D?

Because it is estimated that about half the people living with HIV experience mental illness or substance abuse, we are concerned that people with HIV who rely on antidepressants and antipsychotics will not be able to access their medications. We are also concerned that people with Hepatitis, who we also advocate for, who undergo liver transplants, will not be able to access their immunosuppressants.

Medicare Part D, including the 6 protected classes, is working. It is enabling the elderly and the disabled to access the medications their providers prescribe, and at the same time, saving and prolonging countless lives. We see no reason to change the protected classes, and urge the administration to withdraw this proposal.

We are encouraged by CMS statements this morning they are—that they are sensitive to and are carefully listening to our concerns. Hopefully, in the end, they will do the right thing for patients.

Thank you.

[The prepared statement of Mr. Schmid follows:]

THE **AIDS** INSTITUTE

WRITTEN TESTIMONY OF
CARL SCHMID
DEPUTY EXECUTIVE DIRECTOR, THE AIDS INSTITUTE
TO THE SUBCOMMITTEE ON HEALTH
HOUSE COMMITTEE ON ENERGY AND COMMERCE
HEARING ON CMS' MEDICARE PART D PROPOSED REGULATION
FEBRUARY 26, 2014

The AIDS Institute, a national public policy, research, advocacy, and education organization, is pleased to offer our views on the Centers for Medicare and Medicaid Services' (CMS) proposed Medicare Part D rule. Since we believe aspects of the proposed rule would erode a patient's ability to obtain the medications that their providers prescribe, we are urging CMS to scrap the proposal to change the "six protected classes". Frankly, just like many of you, we were rather surprised the Obama Administration would propose such a rule given its strong commitment to quality health care, including mental health, and to people living with HIV/AIDS and other illnesses and diseases.

For people with HIV and so many others, new drug therapies have saved millions of lives and prolonged millions more. The advent of antiretroviral medications in the late '90s turned HIV from a near certain death to a more manageable disease if patients have access to quality care and medications. We know that all medications are not the same and each person reacts differently to a particular medication. Doctors and patients together make careful decisions about which therapies are most appropriate on a case by case basis. Some individuals may

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develop side-effects to a particular drug, while another person may need a certain therapy to avoid a harmful interaction with a drug being taken for another health condition. For people with HIV drug resistance can occur, requiring them the ability to switch to another drug without interruption.

It was for these reasons that when Medicare Part D was first implemented, CMS determined that a minimum of only two drugs in a class was simply not enough for certain patients, including those with HIV, mental illness, cancer, epilepsy, and those undergoing organ transplantation. The "six protected classes" was created so that patients could have access to all the drugs in these classes.

For the past 10 years, Medicare Part D has been working for millions of seniors and people with disabilities, including over 100,000 people with HIV. As part of the Affordable Care Act (ACA), Congress even further codified the "six protected classes." We see no reason why the protected classes should be changed, and if they were, we would like to see more classes of drugs gain "protected" status rather than reducing them so that more patients can gain access to the medications that are prescribed by their providers.

As I commented earlier, we were shocked when we read the proposed rule. The Secretary used the authority granted to her under the ACA to develop criteria to alter the "six protected classes" and at the same time, proposed to eliminate three of the six classes. One would think that if the Administration was contemplating any changes, the criteria for class review would be developed first with adequate public comment before it was applied. Instead a very arbitrary criterion was developed in secret and then arbitrarily applied at the same time.

Thankfully, the proposed rule continues the protections for antiretrovirals. That would not be the case for antidepressants and immunosuppressants in 2015 and antipsychotics in 2016,

if the proposed rule was finalized. Frankly, we are worried. Who will be next? How much longer will people with HIV, cancer, or epilepsy have access to all the medications they need through Medicare Part D?

Because it is estimated that about half of people living with HIV experience mental illness or substance abuse, we are concerned that people with HIV who rely on antidepressants and antipsychotics will not be able to access their medications. We are also concerned that people with hepatitis who undergo liver transplants will not be able to access their immunosuppressants.

Medicare Part D, including the "six protected classes" is working. It is enabling the elderly and the disabled to access the medications their providers prescribe and at the same time saving and prolonging countless lives. We see no reason to change the "six protected classes" and urge the Administration to withdraw this proposal.

Thank you very much.

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Mr. PITTS. Chair thanks the gentleman. Now recognize Mr. Baker for 5 minutes for an opening statement.

STATEMENT OF JOE BAKER

Mr. BAKER. Thank you, Chairman Pitts, and Ranking Member Pallone, for the opportunity to testify today on the proposed rule for Medicare Advantage and Part D prescription drug plans.

Excuse me. As you know, the Medicare Rights Center is the national nonprofit that works to ensure access to people with Medicare, both older adults and people with disabilities. We answer over 15,000 questions each year from beneficiaries, family, caregivers and professionals, and our Online resources receive more than 1 million visits annually.

I want to stress 3 key points today. First, we believe that each one of the proposed policies reflected in this rule should be evaluated on its own merits, as opposed to supporting or redirecting the entire rule as a whole. We note that the comment period, as has been said, for the rule is still open, and all interested parties should submit comments and give CMS a chance to modify the rule based upon those comments.

In this spirit, I would like to talk about a couple of provisions that we strongly support, and others that we do oppose.

Second, I think the rule reflects CMS' belief that increased oversight and monitoring is required to ensure that Medicare Advantage and Part D plans are adequately serving people with Medicare. We wholeheartedly agree with this determination. In particular, we strongly support CMS' proposal to ensure meaningful differences among Part D plans by further consolidating plan options. On our helpline, we observed that older adults and people with disabilities find choosing among a large number of Part D plans to be a dizzying experience. Most people with Medicare fail to re-evaluate their coverage options on an annual basis. According to one analysis from 2006 to 2010, only 13 percent of beneficiaries switch prescription drug plans during each annual enrollment period, despite changes in premiums, cost sharing and coverage.

So ensuring that there are real meaningful differences between offerings from the same plan sponsor reduces confusion and helps people better comparison shop.

Further related to Part D, CMS acknowledges that Medicare Advantage plans with prescription drug coverage are not adequately coordinating beneficiary care with respect to drug denials. When a Part D drug is denied because it should be covered by Part A or B of the plan, CMS finds that some plans are not adequately informing beneficiaries that their drugs should be covered. This indicates that some plans are not living up to their promise to coordinate care efficiently for their members. To fix this, CMS appropriately suggests new requirements for plans to facilitate access to these medicines.

Throughout the proposed rule, CMS demonstrates a commitment to enhancing transparency. For instance, increased transparency is at the heart of proposals concerning drug pricing fairness, and accuracy with respect to preferred pharmacy. CMS also aims to make information about annual changes to Medicare Advantage and Part D plans more transparent throughout proposals to strengthen ben-

eficiary notices ahead of and during the annual enrollment period. We support these proposals.

Finally, CMS aims to increase oversight and monitoring of prescribing providers to address problems with Medicaid—medication diversion and abusive practices. We appreciate the rule's aim and that it avoids placing burdensome restriction on beneficiary access to needed medicines, but we would like to see additional beneficiary protections in any new system.

Third, we are deeply concerned about CMS' proposed policy to scale-back the protected classes. Specifically, CMS argues that existing beneficiary protections, including the Part D appeals process, will preserve access for beneficiaries if open formulary access is relaxed for antidepressants, antipsychotics and immunosuppressants. Based on our experience counseling Medicare beneficiary, we believe these protections are insufficient, especially the Part D appeals process. Echoing our experience, the 2011 data released by CMS finds that over half of plan-level denials are overturned by the independent review entity; the first time an entity other than the plan reviews the appeal. This alarming rate of reversal raises serious questions about how well the appeals process is working, and demands greater transparencies. We urge members of Congress to request that CMS make plan-level appeals data accessible so that targets for improvement can be identified. In addition, Congress should encourage CMS to improve the Part D appeals process, first and foremost by allowing a beneficiary to receive a formal denial from the Part D plan at the pharmacy counter, as opposed to expecting beneficiaries and their doctors to submit a formal request to the plan for the denial before the appeals process can begin.

Finally, we do believe that pricing is an issue, and CMS is trying to get at that through this proposal. We believe that Congress should restore Medicare drug rebates for beneficiaries that are dually eligible for both Medicare and Medicaid, which would save taxpayers over $140 billion over 10 years.

Thank you for this opportunity to testify.

[The prepared statement of Mr. Baker follows:]

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Testimony of Joe Baker
President, Medicare Rights Center

Prepared for the
United States House of Representatives
Energy & Commerce Committee, Subcommittee on Health

"Messing with Success: How CMS' Attack on the Part D Program Will Increase Costs and Reduce Choices for Seniors"

February 26, 2014

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Introduction:

Chairman Pitts, Ranking Member Pallone, and distinguished members of the Subcommittee on Health, I am Joe Baker, President of the Medicare Rights Center (Medicare Rights). Medicare Rights is a national, nonprofit organization that works to ensure access to affordable health care for older adults and people with disabilities through counseling and advocacy, educational programs, and public policy initiatives.

Thank you for the opportunity to testify on the "Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs" (CY 2015 Part C and D Rule) recently proposed by the Centers for Medicare & Medicaid Services (CMS).[1]

We believe that each of the proposed policies reflected in the rule should be evaluated on its own merits—as opposed to supporting or opposing the proposed rule as a whole. The draft rule reflects CMS' interpretation of multiple statutory mandates as well as updates to existing rules that have become necessary in the two years since a comprehensive Part C and D contract rule has been released.

In short, the evaluation of this rule should not be a zero-sum game, as the rule represents a varied array of changes to Part C and Part D plans that should be assessed on a case-by-case basis. Our testimony will detail proposed policies that Medicare Rights strongly supports, those that we support with suggested changes, those that we approach with caution, and those that we oppose altogether.

Many of the proposed polices that we support reflect CMS' acknowledgement that increased oversight and monitoring is required to ensure that plans and providers serve beneficiaries in a way that is consistent with the purpose and intent of the Medicare program. There are several provisions in the proposed rule where we appreciate CMS' intentions, though we may not agree with the specifics of CMS' proposed policy solutions. In these instances, we offer suggestions to both CMS and Congress that are aligned with the best interests of people with Medicare.

A Direct Line to Medicare Beneficiary Experiences and Challenges:

Medicare Rights answers 15,000 questions on our national helpline each year, serving older adults, people with disabilities, and those that help them—family caregivers, social workers, attorneys, and other service providers. Through our educational initiatives, we touch the lives of another 140,000 people with Medicare and their families. In addition, Medicare Interactive, our online learning tool, receives approximately 1.1 million visits annually.

Problems presented by callers to the Medicare Rights helpline are varied and complex. In 2012, the most common questions heard on the helpline centered on three themes: affording basic health care costs, appealing denials of coverage, and enrolling in Medicare. In all of these areas, we see that Medicare beneficiaries lack needed support.[2]

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[1] "Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs; Proposed Rule" 79 Fed. Reg. 7 (Jan. 10, 2014) pp. 1918-2073 (to be codified at 42 CFR Parts 409, 417, 422, et al.) (Here and after as proposed rule)

[2] Sutton, C., Bennett, R., Sanders, S., and F. Riccardi, "Medicare Trends and Recommendations: An Analysis of 2012 Call Data from the Medicare Rights Center's National Helpline," (Medicare Rights Center: January 2014), available at: http://www.medicarerights.org/policy/priorities/2012-medicare-trends/

As an acknowledgement of our counseling expertise, the Medicare Rights helpline is referenced on a number of standardized beneficiary notices approved by CMS. These include the Medicare Advantage (MA) notice of denial of payment, the MA notice of denial of medical coverage, the Part D notice of coverage denial, and most recently the integrated denials notice developed for use by health plans serving dually eligible beneficiaries.[3]

Medicare Rights regularly provides comment on proposed regulation and educational content developed by CMS, such as the annual Medicare & You handbook. Our commentary on the proposed CY 2015 Part C and D rule draws directly from 25 years of experience serving older adults and people with disabilities who rely on Medicare for basic health security.

Proposed Policies We Strongly Support:

Ensuring meaningful differences between Part D plans. Under Part III, A, Section 20 of the rule, CMS proposes to limit the number of prescription drug plans (PDPs) that can be offered by a plan sponsor to one basic and one enhanced plan per region. We have been consistently supportive of CMS's efforts to consolidate Part D plan offerings and to require meaningful differences among plans, and we strongly endorse the proposed change.

Like CMS, we believe that an appropriate offering of plans in a given region must reflect a balance between meeting the needs of diverse beneficiaries and avoiding undue confusion resulting from the availability of too many plans. Based on our experience, the current multitude of plan choices does not adequately strike the desired balance. In 2013, on average, beneficiaries had a choice among 31 PDPs.[4]

We observe that older adults and people with disabilities find choosing among a large number of Part D plans a dizzying experience. We urge people with Part D to revisit their plan's coverage each year, as annual changes to plan premiums, cost sharing, utilization tools, and formularies are commonplace. Yet, research and our one-on-one counseling of people with Medicare suggest that inertia is widespread.

Most people with Medicare fail to reevaluate their coverage options on an annual basis, largely because there are *too* many options and *too* many variables to compare. According to one analysis, from 2006 to 2010, only 13% of beneficiaries switched prescription drug plans during each annual enrollment period, despite changes in premiums, cost sharing, and coverage.[5]

In addition, so-called enhanced Part D plans are not always meaningfully enhanced, and in many cases it would serve beneficiaries better for these plans to be consolidated or eliminated. Lower income beneficiaries who are enrolled in the Low-Income Subsidy, or Extra Help, can receive full subsidies for so-called basic plans—but not

[3] CMS, "Notice of Denial of Payment,"(required use by November 2013), available at: http://www.cms.gov/Medicare/Medicare-General-Information/BNI/Downloads/NDP.zip; CMS, "Notice of Denial of Medical Coverage," available at: http://www.cms.gov/Medicare/Medicare-General-Information/BNI/Downloads/NDMCZip.zip; CMS, "Notice of Denial of Medicare Prescription Drug Services," (last revised February 2013), available at: http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS10146.pdf; CMS, "Integrated Denial Notice Form," (issued August 2013), available at: http://www.cms.gov/Medicare/Medicare-General-Information/BNI/MADenialNotices.html

[4] Hoadley, J., Summer, L., Hargrave, E., and Cubanski, J., "Medicare Part D Prescription Drug Plans: The Marketplace in 2013 and Key Trends, 2006 – 2013" (Kaiser Family Foundation: December 2013), available at: http://kff.org/medicare/issue-brief/medicare-part-d-prescription-drug-plans-the-marketplace-in-2013-and-key-trends-2006-2013/

[5] Hoadley, J., Hargrave, E., Summer, L., Cubanski, J., and T. Neuman, "To Switch or Not to Switch: Are Medicare Beneficiaries Switch Drug Plans to Save Money?" (Kaiser Family Foundation: October 2013), available at: http://kff.org/medicare/issue-brief/to-switch-or-not-to-switch-are-medicare-beneficiaries-switching-drug-plans-to-save-money/?special=footnotes - footnote-87213-9

for enhanced plans. This means that the less robust enhanced plans will tend to attract a wealthier, healthier population, and be able to offer enrollees lower premiums—while basic plans will charge higher premiums to cover the costs of a by and large less affluent and less healthy population.

Additionally, plan sponsors have less competitive incentive to keep basic plan premiums low—premiums which are paid in large part by the federal government through the Extra Help program. This is because plans sponsors are currently able to attract healthier, private-paying individuals to a low-premium enhanced plan. Medicare Rights agrees with CMS that this kind of risk segmentation should be avoided.

Increasing drug pricing transparency, fairness and accuracy: In Part III, A, Sections 25, 26, 27 and 29, CMS proposes a series of interrelated proposals on negotiated drug prices, preferred cost sharing, and preferred pharmacies. We strongly support this series of proposals, and we believe these changes will benefit both taxpayers and Medicare beneficiaries.

Standardizing reporting by drug plans on negotiated prices: In sections 25 and 26, CMS proposes to standardize how PDPs report the negotiated price for particular medications, which in turn affects the amount CMS pays plan sponsors. To justify this change, CMS details inconsistencies in how PDPs report negotiated drug prices. For instance, some PDPs are reporting a negotiated price that includes "concessions" from the network pharmacy, essentially price reductions, while others report a higher negotiated price that excludes concessions, and wait until the payment year reconciliation process to report concessions as one-off discounts. CMS explains that the proposed standardization is needed to ensure that PDPs cannot game the system by failing to report network pharmacy concessions in the negotiated price.

As such, we support CMS' efforts to ensure that the reported negotiated price accurately reflects the net agreed-upon price between the network pharmacy and PDP. This practice will not only benefit the Medicare program—and taxpayers—but also improve the accuracy of premium and cost amounts in the Medicare Plan Finder, CMS' online plan comparison tool, allowing beneficiaries to more accurately gauge plan costs and efficiency.

Establishing fair and accurate preferred pharmacy cost sharing: In Section 27, CMS seeks to address existing problems with "preferred pharmacy" arrangements. Medicare Rights' counseling experience reflects a need for increased oversight, clarity, and beneficiary education around these practices, as evidenced by our experience serving Ms. T, a 72 year-old woman and Maryland resident who called our helpline during the 2013 annual election period.

Ms. T is enrolled in a PDP and has relied on her local pharmacy for 40 years. In November, she was notified that her pharmacy would no longer be a preferred pharmacy for her drug plan. Her pharmacist explained that he was unaware of the reason behind the change, and wished his business could retain preferred status. Ms. T called the helpline seeking assistance with finding a Part D plan that "would allow her to use her pharmacy."

Our counselor explained that Ms. T's medications would still be covered at her pharmacy, but that the copayments would likely be higher, because her pahramcy was still in her plan's network but was not "preferred." After completing a Plan Finder search, the counselor determined that Ms. T's cost sharing would increase by over $300 during the year if she continued to visit her long-standing pharmacy with her current drug plan. Unfortunately, other PDPs offered in Ms. T's area offered only moderate savings over these new higher costs, and many had deductibles that were simply unaffordable on her fixed income.

Unfortunately, Ms. T's experience is not uncommon. When Congress enacted Part D it sought to preserve patient access and choice by permitting any willing pharmacy to participate in a network so long as it met the plan's reasonable terms and conditions. In recent years, however, some plan sponsors have formed preferred pharmacy arrangements that are increasingly restrictive and not cost effective. As CMS explains in the proposed rule, the utilization of preferred cost sharing by plan sponsors should reflect a lower total cost for prescriptions to Medicare and to beneficiaries. Currently, however, the promise of savings is not being fully realized.

Numerous CMS studies have found that current sponsors who utilize preferred pharmacy networks, "...have actually offered little or no savings in aggregate in their preferred pharmacy pricing, particularly in mail-order claims for generic drugs..."[6] CMS also found that numerous plan sponsors, and their Pharmacy Benefit Manager (PBM) intermediaries, have conflicts of interest with respect to these pharmacy arrangements. CMS writes, "...we note that most PBMs own their mail order pharmacies, and we believe their business strategy is to move as much volume as possible to these related-party pharmacies to maximize profits."[7]

In this way, plans distort market behavior by lowering beneficiary cost sharing where the full cost of the drug is the same or higher than it would be at a non-preferred pharmacy. Instead of harnessing the power of consumer choice to lower costs overall by aligning lower cost-sharing with lower total cost, the plans divide the interests of individual beneficiaries and the Medicare program in order to increase the profits of related-entity mail order pharmacies. This results in higher Medicare spending overall. Like CMS, we find these facts disturbing, and we agree that these practices reflect inappropriate cost shifting to CMS and taxpayers. As such, we strongly endorse CMS' proposal to revisit the current preferred pharmacy network structure in favor of a minimum savings standard under a preferred cost sharing system.

Medicare Rights also supports CMS' proposed language change to more accurately reflect that preferred cost sharing is applicable to a particular medication at a particular pharmacy, and to avoid confusion about whether non-preferred pharmacies are out-of-network. Understanding how preferred, in-network pricing works is one of the most opaque and confusing aspects of choosing a Part D plan. In our experience, beneficiaries often find the distinction between in-network and out-of-network status difficult to grasp. Preferred and non-preferred status, essentially networks within networks, creates yet another layer that beneficiaries must understand when using their Part D benefits. Given this, we support these efforts by CMS to ensure that plan pricing and cost sharing structures are uniformly explained across plans.

Expanding access to preferred pharmacies and reducing beneficiary costs. Aligned with the proposal to ensure that preferred cost sharing signals consistently lower costs, in Section 29, CMS proposes that any pharmacy willing to meet specified savings goals be allowed to charge preferred cost sharing. Medicare Rights agrees that local pharmacies willing to match competitors' prices should be allowed to charge the applicable cost sharing. For instance, had Ms. T's pharmacy been allowed to participate in preferred cost sharing, she would have retained access to her pharmacy of choice and saved considerably on her annual prescription drug costs.

[6] Proposed rule at 1975
[7] Proposed rule at 1976

Enhancing oversight. In many respects the proposed CY 2015 Part C and D rule reflects CMS' belief that enhanced oversight of PDPs and MA plans is needed to improve the delivery of benefits. Medicare Rights supports CMS' determination that strengthened oversight is needed as follows:

Expanded contract termination authority. In Part III, A, Section 2, CMS proposes prohibiting MA plan sponsors from submitting bids for new plans of the same type in regions where the plan was not renewed due to low enrollment. We support this rule, which will discourage plan sponsors from resubmitting bids for plans not well suited to beneficiaries' needs.

Increased audit and inspection authority: In Part III, A, Section 6, CMS details the criteria by which it determines which Part C and Part D plan sponsors are audited each year, and at the same time acknowledges that limited resources allow the agency to perform annual audits on only 10% of plan sponsors, or 30 of 300 Part D and MA sponsors. We strongly agree that more regular auditing of plan sponsors is needed. Additionally, we urge members of Congress to make the resources available to allow CMS to perform its own independent audits on an appropriate scale.

New requirements for continuity and disaster planning: In Part III, A, Section 16, CMS highlights the experience of beneficiaries affected by Hurricane Sandy as the basis for new planning and service continuity requirements. Medicare Rights' main offices are located in New York City, and we heard directly from beneficiaries unable to secure needed prescriptions and other services in the aftermath of Hurricane Sandy. As such, we strongly support CMS' determination that these continuity plans should be developed and tested to ensure that beneficiary needs are met.

Required experience for new plan contracts: In Part III, A, Section 17, CMS develops new requirements for first-time applications to the Part D program. Under the proposed rule, plan sponsors or related entities must have at least one year of experience delivering the Part D benefit in order to a secure a Part D contract. We support these requirements, as beneficiaries will be better protected and served by Part D plan sponsors and entities with experience operating this specific benefit.

Enforcing plan improvement via star rating metrics. In Part III, C, Section 1, CMS proposes including the requirement that MA and Part D plan sponsors achieve good or improving scores on CMS performance standards for outcomes, intermediate outcomes, process, patient experience, and patient access to care in the sponsor's plan contracts. We appreciate and support this recognition of the importance of explicit and enforceable metrics for judging plan performance.

Strengthening Beneficiary Notices. CMS proposes several changes to improve beneficiary notification pertaining to Part C and Part D plans. Specifically, in Part III, A, Section 11, CMS will codify existing requirements that Part D plan sponsors make an Annual Notice of Change (ANOC) available to beneficiaries 15 days prior to the Medicare annual election period, thus aligning Part D requirements with MA rules. While many Part D plans already provide this notice, as required through CMS guidance, we believe it is important that this requirement is made explicit through the rulemaking process.

Requiring an ANOC on Part D plans ahead of open enrollment serves the dual purpose of reminding beneficiaries to revisit their prescription drug coverage options annually, while also providing a summary of changes to a plan's coverage and cost sharing for the following year. Access to this information ahead of open enrollment is critical given that annual changes to premiums, cost sharing, utilization tools, and benefits are

commonplace. Additionally, CMS appropriately emphasizes that PDPs must clearly communicate cost sharing changes, in addition to formulary changes, through the ANOC.

In Part III, A, Section 12, CMS proposes to require that MA plans send the ANOC separate from the Evidence of Coverage (EOC), a detailed list of plan benefits and cost sharing. The EOC is a long and detailed document, and we often observe that beneficiaries find reviewing the EOC a daunting experience. In fact, we find that many beneficiaries require assistance from a trained counselor to decipher the EOC's content. By contrast, the ANOC is a streamlined tool designed to help beneficiaries determine whether or not switching to another MA plan or to Original Medicare during the open enrollment period would be a beneficial choice. As such, we support CMS' recommendation to separate the delivery of the ANOC and the EOC.

We continue to believe that individually tailored ANOCs would be most helpful to beneficiaries as a decision-making tool, and encourage CMS to consider opportunities to further tailor these notices to individual needs. Along these lines, we applaud improvements to the ANOC for MA plans in the "Advance Notice of Methodological Changes for Calendar Year (CY) 2015 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2015 Call Letter," which specifically strengthens requirements regarding plan notification on the potential for provider network changes.[8]

Strengthening MA plan requirements for Part D denials otherwise covered under Part A or Part B. CMS cites cases where a Medicare Advantage Prescription Drug (MA-PD) plan enrollee experiences delays accessing a needed medication, either at the pharmacy counter or through the coverage determination process, that should be covered under Part A or Part B of their plan benefit as opposed to Part D. Like CMS, Medicare Rights agrees that these cases represent a failure on the part of the MA plan to adequately coordinate patient care, and we have assisted helpline callers in these exact circumstances.

One of our callers, Ms. P, a 59-year old woman from Ohio who lives with Chronic Obstructive Pulmonary Disease was turned away at the pharmacy when an anti-asthmatic medication that she uses with a nebulizer was denied under her MA-PD plan's Part D benefit. Only after her physician sent an unsuccessful request for a coverage determination and a subsequent request for a tiering exception was it made clear to Ms. P that payment should have been made under the plan's Part B benefit. Her plan's inability to adequately coordinate care and communicate coverage rules caused a multi-day delay in access to her anti-asthmatic medication, increasing the risk of costly and life-threatening emergency intervention.

To rectify this behavior and help more beneficiaries like Ms. P, in Part III, C, Section 2, CMS proposes requiring that MA-PD plans take steps to appropriately address Part D denials of coverage for medicines that should be covered under Part A or Part B. CMS suggests that MA-PD plans should more effectively coordinate with network pharmacies and providers and ensure that coverage determinations are processed correctly and only once.

We strongly support these proposals, but suggest that CMS extend these requirements to both non-network as well as network pharmacies. Additionally, we continue to urge CMS to make needed improvements to the Part D appeals process, both by improving beneficiary notification and by streamlining the process, most importantly

[8] CMS, "Advance Notice of Methodological Changes for Calendar Year (CY) 2015 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2015 Call Letter," (February 2014), available at: http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2015.pdf

by requiring plans to treat the presentation of a prescription at the pharmacy counter as a request for a coverage determination.

Proposed Policies We Support with Changes:

Addressing improper prescriber practices. In Part III, A, Section 31, CMS acknowledges multiple instances of improper prescribing of medications in the Medicare program and notes that these prescribing practices result in unnecessary Medicare spending. Medicare Rights supports CMS' efforts to reduce this waste, fraud, and abuse by targeting those most likely to be acting inappropriately. We applaud efforts that target problematic providers and suppliers in a narrow and focused way, and that do not impose burdensome, expensive, and ineffective restrictions on beneficiary access to needed care.

In particular, we strongly endorse the requirement that prescribing providers have a Drug Enforcement Administration (DEA) certificate in addition to state prescribing authority to participate in the Medicare program. We also support the standards for continued participation in the Medicare program, and the ability of CMS to revoke participation for abusive behavior that threatens the health and safety of Medicare beneficiaries, though we would like to see enhanced beneficiary protections included. And, although we appreciate the increased oversight and credentialing that the provider enrollment requirement affords, we encourage CMS to amend the rule to avoid unintended adverse affects as follows:

- Hold beneficiaries harmless from the consequences of non-coverage for a non-compliant provider for at least one prescription fill;
- Require MA and Part D plans to reach out to the beneficiary and provider to explain the issue, allowing sufficient time for the beneficiary to see another provider or for the provider to correct their enrollment status;
- Make exceptions for those providers who do not normally see Medicare beneficiaries or receive Medicare payment, including dentists, psychiatrists, and Veteran's Administration doctors.
- Allow these excepted providers to, within a grace period, register with Medicare in a limited capacity to enable them to write prescriptions for Medicare beneficiaries;
- Reach out to policymakers in states that permit foreign prescriptions to determine what kind of alternate provider credential checking might be available to ensure that beneficiaries who spend portions of the year in other countries can access their medications without interruption; and
- Make easily searchable lists of provider status available to Medicare beneficiaries, consumer advocates, and counselors, as well as to MA and Part D plans.

Increasing access to the Medication Therapy Management (MTM) programs. CMS proposes expanding the population to which MTM programs must be offered in Part III, A, Section 15. It is generally acknowledged that Medicare's MTM programs are not living up to desired expectations, and it remains difficult to gauge the relative success of MTM programs, given lower than expected enrollment and limited evidence on the program's efficacy.[9]

[9] Rucker, L.N., "Medicare Part D's Medication Therapy Management: Shifting from Neutral to Drive," (AARP Public Policy Institute: June 2012), avaialble at: http://www.aarp.org/health/medicare-insurance/info-06-2012/medicare-part-d-mtm-AARP-ppi-health.html

Many callers to Medicare Rights' helpline, even those enrolled in MTM programs, are unclear about what the programs are and how they will benefit from enrollment. Common questions from our callers include: How will MTM help me save money on prescription drugs? Is it even "worth it" to enroll in MTM? These questions reflect a general lack of understanding about how MTM programs can assist beneficiaries in managing multiple medications.

We share CMS' concern that plans have not been effective in reaching the beneficiaries who would most benefit from MTM services, and we find evidence cited in the proposed rule on racial and ethnic disparities in access to MTM programs particularly alarming. Based on the research detailed in the proposed rule, we believe CMS' proposal to require that plans offer MTM services to individuals with two chronic conditions who are using at least two Part D prescription drugs a reasonable one and we endorse its adoption.

Although we question whether broad expansion is the best way to enhance the effectiveness of MTM programs, we appreciate that uniformity across plans is needed to facilitate research on program efficacy, best practices, and potential enhancements. We believe that the proposal for expansion would be strengthened with additional monitoring by CMS on MTM participation among the following populations: communities of color, beneficiaries with limited English proficiency, and other hard-to-reach subgroups. MA and Part D plans should be held responsible for their outreach to these groups and for their effectiveness in delivering MTM benefits.

Proposed Policies We Oppose and Areas of Concern:

Scaling back the protected drug classes. In Part III, A, Section 14, CMS proposes replacing the requirement that all Part D plans cover all available medications in six designated protected classes with a two-step test to determine which categories of medications are of sufficient clinical concern to merit continued protected access. Upon application of this test, CMS determines that antidepressants, immunosuppressants, and antipsychotics no longer meet the requirement for enhanced protections.

CMS' proposed rule relies on the appropriate functioning of beneficiary protections, including formulary transparency, formulary requirements, reassignment formulary coverage notices, transition supplies and notices, and the coverage determination and appeals processes, to justify easing robust formulary requirements for protected drug classes. Medicare Rights' experience serving Medicare beneficiaries suggests, however, that these protections are insufficient. In particular, we have continuously suggested that CMS critically examine and streamline the Part D appeals process, and we believe increased transparency about how well the appeals system operates is needed.

Given the shortcomings of the appeals process and other beneficiary protections, namely formulary transparency and transition supplies, we cannot support the proposed changes to the protected classes at this time. Our specific concerns include the following:

The Part D appeals process needs significant repair. In 2012, over one third (33%) of calls to the Medicare Rights helpline concerned denials of coverage and appeals, making up the largest proportion of inquiries to the helpline. Recent findings by MedPAC confirm that many beneficiaries are unaware of their right

to appeal and do not know how to go about initiating the appeals process.[10] We observe the following trends with respect to Part D appeals:

First, we find that people with Medicare are not provided individualized information or adequate education when refused a medication at the pharmacy counter. As such, beneficiaries must embark on a tedious, fact-finding search to learn the reason for the refusal and to determine the best path forward. Pharmacists may have limited or incomplete information and can only direct a beneficiary to call the drug plan for the denial reason. Beneficiaries often face long call wait times and inconsistent customer service when trying to obtain this information.

Next, we observe that the multi-step Part D exceptions and appeals process proves onerous and time- consuming for beneficiaries, pharmacists, and prescribing physicians. Although denied coverage at the pharmacy counter, this refusal does not constitute a formal denial by the plan, which would entitle the person to an appeal. Instead, with the support of the prescribing physician, a beneficiary must formally make an exception request. Only upon receipt of a written denial in response to this request, known as the coverage determination, is the beneficiary permitted to request a formal appeal, termed a redetermination.

While this multi-step process is described clearly here, it is important to note that this course of action may involve multiple phone calls and long wait times, often up to many days, for beneficiaries seeking access to a needed medication. A person must correspond with both their plan and their prescribing doctor on multiple occasions to see the coverage determination and redetermination phases through.

The current system is constructed in such a way that Part D drug plans are effectively granted three chances to make a correct determination about covering a prescribed medication: at the pharmacy counter, in the coverage determination, and in the redetermination. It is worth noting that this three- step process is distinct from Medicare Advantage (MA), Original Medicare, and Medicaid appeal frameworks. In these health programs, a beneficiary receives a notice of non-coverage after a service is received or prior to the service because it is not authorized. Unlike Part D, beneficiaries are not expected to formally request notice of non-payment after refusal of a service.

To date, there is no data or analyses available to the public or reflected in the proposed rule to suggest how often improper denials are corrected at the plan level. Further, what appeals data exists is not reassuring. CMS's 2012 audit suggests that Part D plans struggle most with managing coverage determinations, appeals, and grievances. Additionally, 2011 data released by the agency finds that over half (54%) of plan-level denials are overturned by the Independent Review Entity (IRE), which conducts the first post-plan level—and truly independent—review.

This alarming rate of reversals by the IRE, coupled with CMS' own audit data on plans, raises serious questions about how well the redetermination and appeals process is working, and demands greater transparency. We urge members of Congress to request that CMS make plan-level appeals data accessible in easy-to-comprehend formats so that targets for improvement can be identified.

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[10] Presentation by Sokolovsky, L., Suzuki, S. and L. Metayer, "Part D exceptions and appeals" (September 2013), available at: http://www.medpac.gov/transcripts/part_d_exceptions_&_appeals.pdf; CMS, "Fact Sheets: Part D Reconsideration Appeals Data, Part D Fact Sheets CY 2011" (2011), available at: http://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Reconsiderations.html

More importantly, we strongly believe that the Part D appeals process must be streamlined and tested ahead of any changes that would relax the protected classes. A straightforward approach to improving the appeals process would combine a point-of-sale refusal with a formal request for a coverage determination, as suggested in a recent letter to CMS signed by members of the Senate Finance Committee.[11] Allowing the pharmacy counter refusal to serve as the coverage determination serves the dual purpose of removing a burdensome step for beneficiaries and their doctors while also expediting the appeals process for those who need it.

Formulary review and transparency need improvement. We believe that CMS sets an unreasonably low bar for evaluating beneficiaries' formulary needs. In the proposed rule, CMS writes, "...with our more than 7 years of experience with the Part D program, we are not aware of any Part D drug that is not included on at least one Part D formulary. Thus, beneficiaries who review plan formularies [on Plan Finder] can select plans that cover all of their current medications."[12] This statement is highly problematic as justification for reducing formulary protections for two key reasons:

First, it is inconsistent with Medicare Rights' experience helping tens of thousands of beneficiaries review their coverage options. While it may be accurate that there is no Part D drug that is not on at least one formulary, the same plan options are not available in all areas of the country, and beneficiaries must select a Part D plan within their geographic area. Furthermore, many beneficiaries, particularly those with complicated health status, take more than one prescription. The fact that drug A is on the formulary of Plan X and drug B is on the formulary of Plan Y is not sufficient for a person who must take both A and B.

Second, this statement ignores the well-documented shortcomings of the Plan Finder tool. As a recent GAO report found, despite CMS oversight and improvements, beneficiaries still encounter inaccurate and out-of-date information on Plan Finder.[13] On an annual basis, Medicare Rights provides detailed recommendations to CMS about needed improvements to Plan Finder, drawing directly from our experience serving 2,500+ beneficiaries during the open enrollment period. Among our recommendations are to add appropriate MA plan content, most notably information concerning provider networks, ensure the clarity and accuracy of mail order information, improve the accuracy of cost sharing data, and more.[14]

We believe that CMS should take steps to improve both beneficiary education and Plan Finder before restricting access to some of the most urgently needed medications. Members of Congress should explore how to make the appropriate resources available to CMS to support making the Plan Finder a more robust and user-friendly tool.

Access to transition fills is inconsistent. Transition fills, coverage for one month for a continuing treatment when there has been a plan or formulary change, are an essential protection that we find many beneficiaries do not receive. In 2013, CMS continued a transition-fill monitoring program in response to widespread failure to provide appropriate transition refills to those entitled to them.[15] CMS has attempted to

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[11] Thomas, K. and R. Pear, (February 21, 2014) "Plans to Limit Some Drugs in Medicare is Criticized," *New York Times*, available at: http://www.nytimes.com/2014/02/22/business/plan-to-alter-medicare-drug-coverage-draws-strong-opposition.html?_r=0

[12] Proposed rule at 1939

[13] GAO, "CMS Has Implemented Processes to Oversee Plan Finder Pricing Accuracy and Improve Website Usability," (January 2014), available at: http://www.gao.gov/products/GAO-14-143

[14] Medicare Rights Center, "MEMO to the Centers for Medicare & Medicaid Services re: Plan Finder Observations during Fall Open Enrollment: October 15, 2012 – December 17, 2012," (March 2013)

[15] CMS, "MEMO re: Contract Year 2013 Part D Transition Monitoring Program Analysis." (December 2012), available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/ContractYear2013PartDTransitionMonitoringProgramAnalysis.pdf

address failures to properly effectuate transition fill by drug plans in the past, without improvement. These systematic failures underscore the need for on-formulary access to a wide range of medications for certain classes of drugs.

Uninterrupted treatment on a specific medication is particularly essential for antidepressants, antipsychotics, and immunosuppressants, the very same drugs for which CMS suggests protected status should be relaxed. We applaud CMS for implementing the transition-fill monitoring program. Yet, we believe that CMS should wait for the full results, and publish those results, before relying on transition fills as an appropriate fail-safe for securing access to these essential medications.

In addition to these known shortcomings, transition fills are only available to a narrow band of beneficiaries. Individuals previously stabilized on a particular antidepressant, for example, but who are untreated for a period of time are not eligible for a transition fill if they must return to treatment. In these cases, a beneficiary's physician likely knows which specific medication is best suited to the person's health needs. In the absence of broad formulary protections, these beneficiaries may not be able to access the particular medicine essential to their health. In short, transition fills will not adequately protect these beneficiaries from diminished access to needed prescriptions if the protected classes are not preserved.

Targeted interventions are needed for overprescribing in long-term care settings. CMS presents no evidence to suggest that open access to protected classes of medications on Part D formularies results in widespread overutilization, with the exception of inappropriate prescribing of antipsychotic medications in nursing home settings. Like CMS, Medicare Rights is deeply concerned about this trend, and we encourage both CMS and members of Congress to explore targeted interventions in these settings to limit these egregious prescribing practices.

As such, we support CMS' proposed policy to target providers who prescribe antipsychotics for patients with dementia in direct violation of the drug's Food and Drug Administration (FDA) approved black box warning. Additionally, we urge CMS to explore partnerships with state boards that oversee prescriber and nursing facility practices, or to develop targeted, narrow exceptions to the protected class status to allow prior authorization requirements in certain prescription settings. These solutions would target abusive prescribing behaviors in specific settings, rather than jeopardize access for beneficiaries living in community settings who must access these medications.

Congress should seek Medicare drug savings that do no harm to beneficiaries. CMS cites increased drug prices as its primary reasoning behind scaling back the protected drug classes and requiring open drug coverage for specific classes of medications. CMS writes, "The principal disadvantage is that an open coverage policy substantially limits Part D sponsors' ability to negotiate price concessions in exchange for formulary placement of drugs in these categories or classes."[16] CMS's concerns about Medicare's ability to secure the best possible prices on prescription medications are not unfounded. But we do not believe that CMS should pursue policies that may unduly restrict access to rectify this issue.

Instead, Congress should act. To address concerns regarding drug pricing in Medicare, Congress should restore Medicare drug rebates, as reflected in the Medicare Drug Savings Act (H.R. 1588; S.740), and save taxpayers

[16] Proposed rule at1937

$141.2 billion over ten years.[17] Additionally, Congress should explore policy proposals included in the President's recent budgets to accelerate manufacturer rebates to help close the Part D prescription drug coverage gap, prohibit pay-for-delay agreements, and reduce the exclusivity period for biologic drugs. These sensible and straightforward solutions would allow Medicare to save billions on prescription drug costs, without increasing beneficiary costs or restricting access.[18]

Expanding MA reward and incentive programs. In Part III, A, Section 36, CMS suggests allowing MA plans to offer reward and incentive programs to current enrollees to encourage participation in activities that promote improved health, prevent injuries and illness, and encourage efficient use of health care resources. Medicare Rights remains cautious about the expansion of wellness programs, and we are firmly opposed to any wellness program that "incentivizes" participants through penalties, such as higher costs. Research suggests that incentives may increase *participation* in wellness programs, but there is little evidence to suggest that rewards and penalties lead to meaningful changes in health behaviors and outcomes.[19]

Our primary concern is that outcome-driven rewards and incentives programs may disproportionately penalize individuals who already face persistent barriers to maintaining their health and obtaining health care services, including older adults, people with disabilities, communities of color, and low-income patients.[20] As such, we share CMS' concern that rewards and incentives programs may be targeted only at healthy enrollees and that sicker enrollees could be discouraged from participating—and thus from enrolling in an MA plan that offers these programs.

Given these well-documented concerns, we appreciate that CMS proposes requiring that all MA plan enrollees are able to earn rewards without discrimination based on race, gender, chronic disease, institutionalization, frailty, health status, or other impairments. We also appreciate CMS' requirement that plans submit data on these plans at CMS' request. However, we also believe that CMS should solicit data from these programs on a regular basis and should carefully monitor their implementation. In the absence of robust oversight to prevent discrimination based on race, disability, or economic status, and "cherry picking," we are hesitant to support the expansion of these programs.

Other notable areas of concern in the proposed include the following:

Prohibiting the copayment waivers: In Part III, A, Section 9 CMS proposes prohibiting the waiver of cost sharing when a plan sponsor and pharmacy have common ownership. We appreciate the need to enforce anti-kickback and uniformity of benefit rules, but we believe that CMS should enforce compliance with current rules rather than to remove a valuable safety valve. The current narrow exception allows a pharmacy to waive cost sharing on a non-routine basis when a beneficiary urgently needs a medication and is clearly unable to pay. This is an important beneficiary protection that should not be eliminated or reduced.

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[17] Office of the Honorable Senator J. Rockefeller, "Rockefeller and 18 Other Senators Introduce Legislation to Protect Seniors & Reduce Defiction by $141.2 Billion," (April 2013), available at: http://www.rockefeller.senate.gov/public/index.cfm/press-releases?ID=617fffeb-4c5a-4123-a5b3-1f8b790e5f8b

[18] Office of Management and Budget (OMB), "The President's Budget for Fiscal Year 2014," (April 2013), available at: http://www.whitehouse.gov/omb/budget

[19] Adams Dudley, R., Tseng, C., Bozic, K., Smith, W.A., and H.S. Luft, "Consumer Financial Incentives: A Decision Guide for Purchasers, (AHRQ: November 2007), available at: http://www.healthcarevisions.snapmonkey.net/f/2008_AHRQ_Incentive_Report.pdf

[20] Families USA, "Wellness Programs: Evaluating the Promises and Pitfalls," (June, 2012), available at: http://familiesusa2.org/assets/pdfs/health-reform/Wellness-Programs.pdf

Establishing time frames for retroactive premium collection: In the same section, CMS proposes a timeframe to require plans to refund or seek repayment if premium amounts were incorrectly collected. We frequently observe instances when a plan sponsor makes billing errors as a result of mismanagement or poorly designed systems. When errors are discovered, CMS requires plans to send large and unexpected payment demands to beneficiaries, and often low-income beneficiaries cannot afford this expense.

Beneficiaries in these circumstances are often unaware of their right to seek financial hardship exceptions and many simply pay an exorbitant cost, despite the severe financial hardship that results. CMS should set clear limits on how far back plans can retroactively collect premiums that were not billed as a result of plan error, and provide notices to beneficiaries with clear instructions about how to seek relief if payment would cause financial hardship.

Automatic or passive enrollment for Duals Special Needs Plan (D-SNP) enrollees. CMS proposes to passively enroll members of a non-renewing D-SNP into another D-SNP in Part III, A, Section 38. Medicare Rights opposes this change, and prefers the current process of returning the individual into Original Medicare, guaranteeing access to any Medicare provider. Passive enrollment processes are not aligned with the values of choice and informed decision-making central to the success of the Medicare program.

Conclusion:

In conclusion, we hope that members of Congress will support CMS on the proposed policies outlined in this testimony that will improve the Medicare benefit and preserve access to needed health care. Many of the policy revisions suggested by CMS will advance these goals and should be adopted. Among these changes are Part D plan consolidation; increased transparency on drug pricing, fairness and accuracy; enhanced oversight regarding plan experience, terminations, and continuity planning; improved beneficiary notice; and strengthened coordination requirements for MA-PD plans concerning appeals.

At the same time, we hope Congress will raise questions in areas where well-meaning CMS proposals can be improved, most notably with respect to addressing improper prescribing practices and expanding the Medication Therapy Management (MTM) programs. Finally, we hope members of Congress will carefully scrutinize proposed policies that may harm vulnerable beneficiaries, particularly with respect to the proposed rule to scale back the protected drug classes.

We believe that the suggested need to secure better prices reflected in the CY2015 Part C and D rule presents an opportunity for Congress to act, most notably by restoring Medicare drug rebates, a proposal that will save over $140 billion in the Medicare program. Additionally, Congress should use this opportunity to demand greater transparency and ask critical questions about existing beneficiary protections for those enrolled in MA and Part D plans, namely with respect to prescription drug appeals.

Thank you for the opportunity to testify.

MEDICARE RIGHTS

Summary of Testimony by Joe Baker, Medicare Rights Center

The Medicare Rights Center is a national, nonprofit organization that works to ensure access to affordable health care for older adults and people with disabilities through counseling and advocacy, educational programs, and public policy initiatives.

The Medicare Rights Center answers 15,000 questions on our national helpline (800-333-4114) each year, serving older adults, people with disabilities, and those who help them—family caregivers, social workers, attorneys, and other service providers. We believe that each of the proposed policies reflected in the "Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs" rule should be evaluated on their own merits—as opposed to supporting or opposing the proposed rule as a whole.

Proposed Policies We Strongly Support:

- **Ensuring meaningful differences between Part D plans** by requiring that plan sponsors offer one basic plan and one enhanced plan in a given region. The proposed rule will facilitate more informed decision-making by beneficiaries by further streamlining available plan choices.
- **Increasing drug pricing transparency, fairness, and accuracy** through measures designed to ensure that "preferred" pharmacy network status translates to lower costs for consumers and for the Medicare program.
- **Enhancing plan oversight through** expanded contract termination authority, increased audit and inspection authority, new requirements for continuity planning, and enforced plan improvement via star rating metrics.
- **Improving beneficiary notices** through changes to delivery of the Annual Notice of Change (ANOC), which details annual plan changes, and the Evidence of Coverage, a more detailed summary of plan benefits.
- **Strengthening MA plan requirements for Part D denials** by requiring that MA-PD plans ensure coverage for medicines denied under Part D that should otherwise be paid for under Part A or B of the plan.

Proposed Policies We Support with Changes:

- **Addressing improper prescriber practices** by appropriately targeting providers not acting in the best interest or safety of beneficiaries. Additional consumer safeguards are needed to ensure continuity of care as CMS transitions to systems to more closely monitor Medicare providers.
- **Expanding Medication Therapy Management (MTM)** through revised eligibility guidelines. Adequate data collection and monitoring is needed to ensure that plans extend MTM services to diverse and at-risk populations.

Proposed Policies We Oppose and Areas of Concern:

- **Scaling back the protected drug classes** should not be adopted at this time, as existing beneficiary protections, especially the Part D appeals process, are not sufficient to preserve access to essential medicines.
- **Expanding Medicare Advantage (MA) reward and incentive programs** should only be pursued with rigorous oversight and monitoring given well-documented concerns about the potential risk for discriminatory impact and cherry picking.

Mr. PITTS. Chair thanks the gentleman. And we will now go to questioning. I will recognize myself 5 minutes for that purpose.

Dr. Holtz-Eakin, in a recent final regulation issued in April 2011, CMS reiterated the noninterference clause's application to Part D, sponsor pharmacy negotiations, in its response to a comment, "As provided in Section 1860D–11(i) of the Act, we are prohibited from interfering with negotiation between Part D plans and pharmacies."

Dr. Holtz-Eakin, you were at CBO during the time that the Part D Program was operating. How did CBO interpret the noninterference clause that Congress passed in 2003?

Mr. HOLTZ-EAKIN. Well, we were asked on numerous occasions what would happen if the noninterference clause were to be deleted from the law, and indeed shortly after its passage, this is a letter from January 23, 2004, we wrote a letter to then-Majority Leader Frist, which said that striking the provision would affect negotiations between drug manufacturers and pharmacies and sponsors of prescription drug plans. So there is no question that it covered the pharmacies, and there is no question that the kind of action that CMS is proposing in this rule is at odds with the intent of Congress.

Mr. PITTS. In the proposed regulation, CMS has reinterpreted the noninterference clause, clearly outlined in Federal law, such that, in my opinion, the proposed regulation actually contradicts the meaning of the statute.

If CMS can effectively change the meaning of settled Federal law via regulation, then we must ask ourselves what are the outrebounds of the abuse of that authority.

Dr. Holtz-Eakin, could CMS require pharmacies or manufacturers to give them records access?

Mr. HOLTZ-EAKIN. Certainly, they could, and I don't know what the outrebounds are, Mr. Chairman. I am not certainly a lawyer by training, but, you know, the clear intent was to not do what is proposed in this rule, and if they are to go forward with this and not see it struck down by the courts, which I think it very well would be, then there is nothing they can't do to the Part——

Mr. PITTS. Could——

Mr. HOLTZ-EAKIN [continuing]. Part D——

Mr. PITTS. Could CMS set volume caps on prescriptions under Part D?

Mr. HOLTZ-EAKIN. They certainly could.

Mr. PITTS. Could CMS require participating pharmacies maintain stockpiles of certain drugs?

Mr. HOLTZ-EAKIN. Yes, they could.

Mr. PITTS. The Office of the Actuary at CMS produced an analysis of the estimated budgetary impact of the proposed rule, yet they acknowledged in conversations with committee staff that not all elements of the proposed rule had been scorned.

Well, Milliman actually did a complete cost analysis by surveying drug plan sponsors and PBM's to evaluate the anticipated effect of the rule on the Part D Program, and found it would cost billions of dollars. Do you believe that the American public deserves a full cost accounting from CMS on this issue?

Mr. HOLTZ-EAKIN. I do. I believe this rule is so sweeping as to essentially constitute new law, that Congress ask for a budgetary analysis from the CBO before it enacts new law, I think the same thing should be done in this case.

Mr. PITTS. CMS rule proposes that prescription drug plans are limited to offering only 1 standard benefit, and 1 enhanced benefit plan per region, is that correct?

Mr. HOLTZ-EAKIN. That is correct.

Mr. PITTS. So let me ask this, if 2 of my constituents are enrolled in 2 different enhanced benefit plans offered by the same PDP, 1 of those 2 seniors will lose their current prescription drug plan under the proposed rule, isn't that correct?

Mr. HOLTZ-EAKIN. That is correct, and in my written testimony, we have an estimate of the number of seniors who would be affected in each State.

Mr. PITTS. Well, I don't think CMS should be outlawing seniors' current prescription drug plans by placing arbitrary caps on the number of plans that can be offered. CMS should not be taking away the prescription drug plans that seniors rely on today, do you agree?

Mr. HOLTZ-EAKIN. I agree with the principle that seniors should be able to choose, that choice is an important part of our society.

I want to emphasize one of the things I said in my opening. You can't look at that in isolation. The ability to have more plans, gets you more volume and lowers the cost of the program as a whole. And I think the CMS analysis is fundamentally flawed by ignoring that.

Mr. PITTS. All right, thank you. Chair recognizes the ranking member, Mr. Pallone, 5 minutes for questions.

Mr. PALLONE. Thank you, Mr. Chairman.

I wanted to ask Mr. Baker, when Part D was enacted into law, many of us were skeptical the program would work. In fact, we were opposed to turning Medicare over solely to private insurance companies because of concerns with gaming and the ability to fully protect beneficiaries in these plans that may be more interested in corporate profits than patient wellbeing.

Nevertheless, once Part D became the law, Democrats put aside their reservations and have worked hard to ensure that patients get the best deal possible under the law. And I would contrast this with the way the Republicans have behaved since the enactment of the Affordable Care Act, actively trying to undermine implementation of the law and keep consumers from getting access to important program benefits. However, the Affordable Care Act made a number of improvements to Part D, most importantly, it filled in the doughnut hole, and the ACA also made a number of changes to the Medicare Advantage Program, ensuring that consumers and taxpayers get good value for their dollars.

So, Mr. Baker, could you talk briefly about the way the Affordable Care Act has improved Part D and Medicare Advantage for beneficiaries?

Mr. BAKER. Well, once again, you are absolutely right. The closure of the doughnut hole has been a great boom to people with Medicare Part D coverage, and we hear about that on our helpline. As well, with regard to the changes in the Medicare Advantage

Program that have been implemented through the Affordable Care Act, I note the wellness visit that is now covered, preventive care that is now covered, the prohibition about charging higher coinsurance or copayment amounts for care, like skilled nursing facility care or chemotherapy care. This makes sure that there is no gaming amongst the plans, in trying to provide disincentives for folks with, for example, cancer—a history of cancer from joining certain plans, from consolidating offerings, once again, as Mr. Blum referred to, in Part D, but also in the Medicare Advantage Program, there has been a constant effort by CMS under the Affordable Care Act to make sure the plans have meaningful differences. And so that has helped consumers understand the program better and use the program better, I think. And finally, the out-of-pocket cap that CMS has implemented in the Medicare Advantage Program has provided seniors with, I think, great security in knowing that, yes, they have copayments amount but their—copayments amount in Medicare Advantage plans, but they will be capped at a certain amount out-of-pocket, and I think that has done a lot to make the program more attractive to seniors. They flock to Medigap Programs in the context of original Medicare because they see a lot of financial security there for that first dollar of coverage. I think many now see the out-of-pocket maximum to Medicare Advantage as a similar financial security measuring, and so that has made the program more attractive.

Mr. PALLONE. I know that you expressed significant concern with the section of the rule related to categories or classes of drugs of clinical concern and which identify classes of drugs require Part D plans to include all or substantially all covered drugs on their formularies. And you are aware, CMS has indicated that these protected classes of drugs were not necessarily meant to be permanently protected, recognizing now on the one hand in many instances as generics become available, broadly mandating that every drug be available may not make sense, but on the other hand, new classes of drugs may need to be deemed protected to ensure patient access. And as such, the Secretary was directed to establish criteria by which identified classes, including new classes of drugs for inclusion under the protected status.

If you could—I know you are concerned about the Part D appeals process. Can you just basically describe some of the problems that you see with the current appeals process, and why, if the appeals process is not fixed, the protected classes proposal would be especially problematic for patients?

Mr. BAKER. Yes, I would be happy to. You know, first off, this issue that I mentioned earlier about when folks go to the pharmacy counter, they get a denial, and in effect, they are told their drug is not going to be covered and be dispensed to them, but that is not an "actual denial" by the plan. It is not a coverage determination. They then need to either go home or otherwise call or email or somehow contact the plan to actually get a coverage determination and denial, and this can take a lot of time, it can take a lot of calls. So we are really calling for that denial at the plan counter to be the denial or coverage determination that does help them initiate and allow them to initiate an appeal. So that is one issue there.

There are also then 2—at least 2 levels of redetermination that the plan has in addition to that denial at the pharmacy counter. We believe that could be slimmed to get to the independent review entity sooner. I think also we are also concerned generally that there is not a lot of data about how plans internally are dealing with appeals, and we think that information, some of it could be publicly available, and could help consumer gage whether or not plans are doing a good job by those who have problems with the plans' determinations.

Mr. PALLONE. All right, thanks a lot.

Mr. PITTS. Chair now recognizes the vice chairman of the committee, Dr. Burgess, 5 minutes for questions.

Mr. BURGESS. And I thank the chairman.

I would offer for those limited comparisons between ACA and the Medicare Modernization Act from 10 years ago. There are some significant differences, of course. The Medicare Modernization Act was not the coercive, broad, overreaching legislation that the ACA was. There was difference in scope and size, and thus, the implementation, while there may be similarities, there are also vast differences.

Mr. Schmid, just like you, to say I was blindsided by this rule would be an understatement. I thought things were working reasonably well. I don't understand the discussion, why we are even having the discussion about dispensing with any of the 6 protected classes. And Dr. McClellan came here and very patiently, in 2005 and 2006, very patiently went through what the reasons were for developing those classes. I think you heard Dr. Murphy talk about the—on the psychiatric side. I have discussed on the immunosuppressant side. You have very eloquently discussed on the—with the antiretroviral drugs, why these are important to have these as protected classes. And I really cannot—and I don't—I did not hear from Mr. Blum why there was a reason for doing this, so I agree with you. I am completely blindsided by the rule.

Dr. Holtz-Eakin, I mean, Chairman Pitts asked you this to some degree already, but let me just ask you again: What—in your opinion, what was the original intent of the noninterference clause?

Mr. HOLTZ-EAKIN. Its intent was to make sure that, on both sides of the negotiations, that plans had the unfettered ability to negotiate aggressively with drug manufacturers, and to structure their plans and their pharmacy networks to attract the volume necessary to get good deals with the manufacturers. And the idea was to keep the Congress and the administration out of those negotiations.

Mr. BURGESS. So if we are doing away with the noninterference clause, perhaps we are instituting an interference clause. Would that be a logical assumption?

Mr. HOLTZ-EAKIN. I view this as direct interference in negotiations. I don't see any other way to read it. If I negotiate with you, and then turn around and CMS orders me to give him the same deal, that is a pretty clear interference. I don't understand that.

Mr. BURGESS. Well, of course, Congress loves to interfere, so that will give us an opening.

Mr. HOLTZ-EAKIN. I would encourage you to restrict those impulses please.

Mr. BURGESS. Well, that is, of course, why we are having this discussion, but it would—I mean that interference—then if we label that the interference clause, the interference clause is going to have an effect on the direct cost to beneficiaries, is it not?

Mr. HOLTZ-EAKIN. It is. I mean the core costs are the pharmaceuticals, and the deal that can be cut with the manufacturers is at the heart of the cost of the program. Things that impair the ability of plans to cut good deals are going to raise the cost to everybody; beneficiaries, taxpayers, it is going to show up somewhere.

Mr. BURGESS. And I was going to make that point. It is not just the beneficiaries, obviously, the person who is ultimately paying the bill, which is the United States taxpayer, or our generations to follow, since some of it is not paid for immediately, they will all be affected by the institution of an interference clause where none existed before. Is that a correct statement?

Mr. HOLTZ-EAKIN. That is correct.

Mr. BURGESS. So the proposed CMS rule suggests that, for a competitive market to function, that they, Centers for Medicare & Medicaid Services, have a duty to ensure that there is a competitive market, and encourage elements to promote competition. So maybe as a professor in economics, you can tell us how this interference would promote competition.

Mr. HOLTZ-EAKIN. I don't think it is pro-competitive. If you take, for example...

Mr. BURGESS. Well, but between members of Congress, wouldn't it?

Mr. HOLTZ-EAKIN. Well, just for a second. Just a narrow provision, you know, the idea that any pharmacy should be able to provide at the terms negotiated between and plan and its preferred pharmacy network, there is already competition. Anyone can right now go to any pharmacy and get their prescription filled. They may not get the terms from the preferred network but they can go. That forces those who are not in the network to compete on nonpriced grounds; service, variety of things in the store, whatever it may be. That is how economics works. For them to step in and interfere undercuts that competition.

Mr. BURGESS. And I, again, don't mean to interrupt you, but the time will draw short.

And that competition is what gave us the $4 prescription at Wal-Mart, and then other chains followed suit with that. Those are indirect effects of the Medicare Part D law that oftentimes no one discusses. So——

Mr. HOLTZ-EAKIN. Yes, I think that is one of the reasons it came in under budget cost. I mean, we thought the competitive incentives were quite strong with CVL, we did, but a couple of things happened that we didn't anticipate. One is we never had any trouble getting sponsors to enter. There was a fear of having to have government fallback plans, those were priced in there. None of that ever happened, however competitive incentives. And the second was the network size, the pharmacy and the savings in the pharmacies were bigger than we expected.

Mr. BURGESS. And just as a consequence to that, I mean and Mr. Blum testified to the fact that costs came in lower, he thought because of generic prescribing. I will tell you that I think that generic

prescribed existed because of the so-called coverage gap, or doughnut hole. Now that we have done away with that, or we will do away with that in future years, what is going to happen to that driver that kept costs low?

Mr. HOLTZ-EAKIN. Well, and I know you are over, but briefly, I don't think his reading of the record is correct. The biggest difference between the projections and reality was lower enrollment. Fewer bodies are cheaper, and that is the top thing, not generics. Generics are in there, but there was a lot of generic substitution anticipated because a lot of the patented pharmaceuticals were going to go off patent over the first 10 years. We knew that so that was priced in at the outset, so it is not really a surprise in the data.

Mr. BURGESS. Very good.

Thank you, Mr. Chairman. I will yield back.

Mr. PITTS. The Chair thanks the gentleman. Now recognize the gentleman from Texas, Mr. Green, 5 minutes for questions.

Mr. GREEN. Thank you, Mr. Chairman.

Mr. Baker, you have heard from Mr. Holtz-Eakin's testimony certain estimates suggest that a large number of beneficiaries would lose their current plan due to CMS' proposal to level the playing field for pharmacies wishing to offer preferred cost sharing under a plan's preferred network. To me, this doesn't sound right. Expanding the availability of pharmacies can often reduce cost sharing as long as they can meet negotiated price, only seems to expand access to other places. And it is reasonable to expect that allowing any pharmacy to match the competitive prices offered by preferred pharmacies would result in more competition and better access to lower-priced drugs for seniors. It also would seem to help beneficiaries who prefer to retain trusted relationships with community providers at their local pharmacy, as well as beneficiaries who do not have nearby access to a big box retailer.

And my question, Mr. Baker, can you confirm this line of reasoning? Has it been your experience that all beneficiaries can currently access preferred networks and preferred pricing, or are some of them left out in the cold?

Mr. BAKER. It is our experience that some—in our written testimony, our longer, written testimony, we do talk about a woman in Maryland who did not, you know, lost access to her local pharmacy because they were not able to provide the preferred pricing that she could get at another pharmacy where she had not had a 40-year relationship with that pharmacy. So we do believe that opening up, just as we have any willing provider in the general networks in the Part D plans opening up, that any willing provider in preferred networks will expand options and access for consumers, and we certainly are supportive of that proposal.

Mr. GREEN. So you agree with helping beneficiaries get access to more pharmacies that provide reduced cost is good for those patients?

Mr. BAKER. Yes, I do.

Mr. GREEN. OK. It seems that pharmacies who have contracts today really don't want to compete with community pharmacies who are prohibited now. Would you comment on this? Wouldn't allowing participating of any pharmacy who can meet the plan's

terms and prices actually help competition and improve access for patients?

Mr. BAKER. I think that, you know, certainly, as Mr. Holtz-Eakin was saying, there are other components on which pharmacies can compete at such a service, et cetera, what is in the front of the house, as it were, and not at the pharmacy counter, but we do believe expanding access by allowing community pharmacies and others to be able to match preferred prices will spur further competition, and certainly increase access and decrease cost for consumers, and hopefully for the program itself.

Mr. GREEN. Well, I would have—I think I remember, because I was on the committee when we did this in '03, it was a very long markup, same with the Affordable Care Act, and I think there was an amendment to this effect that was part of that, and I am trying to—I will go back and look at the records, but I understand that, you know, when we deliver healthcare for doctors, you know, the office visit is basically the same, you know, if you go have a certain procedure, it is basically the same. And, now, granted, we do have preferred providers on certain things, but that is not—that is through an insurance policy, not necessarily through Medicare, but—so anyway.

I want to yield back to—yield my time to the ranking member.

Mr. PALLONE. Thank you. Mr. Baker, I wanted to ask, I didn't get a chance, that while you have concerns with the Protected Classes Policy, you still do believe that many of the other provisions in the rule that protect patients should go forward, is that correct?

Mr. BAKER. Yes, we do.

Mr. PALLONE. All right, thank you. I yield back.

Mr. PITTS. The Chair thanks the gentleman. Now recognizes the gentlelady from North Carolina, Mrs. Ellmers, 5 minutes for questions.

Mrs. ELLMERS. Thank you, Mr. Chairman, and thank you to our panel.

Dr. Holtz-Eakin, I have a question for you that is North Carolina-specific. I am very concerned with the number. I think with—this proposed rule has a potential of affecting over half a million of my seniors. Do you know how many of those healthcare plans, I mean in your numbers and in your research, do you know how many plans will be eliminated as a result of this in North Carolina?

Mr. HOLTZ-EAKIN. We have an estimate that we would be happy to get to you. When we——

Mrs. ELLMERS. OK.

Mr. HOLTZ-EAKIN [continuing]. Did our analysis, we found out the number of beneficiaries in North Carolina——

Mrs. ELLMERS. Um-hum.

Mr. HOLTZ-EAKIN [continuing]. We then looked at the plans in North Carolina, especially the large plans, we could identify those that had preferred pharmacy networks that would be eliminated——

Mrs. ELLMERS. Um-hum.

Mr. HOLTZ-EAKIN [continuing]. Or other plans that would be eliminated, and we can get that to you.

Mrs. ELLMERS. Great, thank you. I would appreciate that. You know, there was a Milliman study done, a survey analysis in January 2014, CMS Medicare Part D proposed rule, found that approximately 12.9 million Medicare Part D beneficiaries currently enrolled in preferred pharmacy PDPs may experience material premiums and cost-sharing increases in 2015 as a result, on average, because of the proposed rule.

Do you think this is right, is it 12.9 million seniors will be affected this way? What are your thoughts on that?

Mr. HOLTZ-EAKIN. It doesn't surprise me. I don't know if the precise estimates——

Mrs. ELLMERS. Um-hum.

Mr. HOLTZ-EAKIN [continuing]. The right one, but if you change the terms the way the rule proposes, there is not really anything known as a preferred pharmacy anymore.

Mrs. ELLMERS. Yes.

Mr. HOLTZ-EAKIN. So a plan can't go to pharmacy——

Mrs. ELLMERS. Pretty much just goes to—yes.

Mr. HOLTZ-EAKIN. Right, and so they can't cut as good a deal, the——

Mrs. ELLMERS. Um-hum-

Mr. HOLTZ-EAKIN [continuing]. Cost sharing will go away and the prices—the net price to consumers will go up.

Mrs. ELLMERS. Which is exactly what I am hearing today as we are doing this subcommittee hearing, is there are 2 trains of thought that somehow we are going to be saving money——

Mr. HOLTZ-EAKIN. Right.

Mrs. ELLMERS [continuing]. And yet it is contradicting each other, that by doing this we are actually going to be saving money, and yet we keep seeing that it is actually not going to be the case.

Mr. HOLTZ-EAKIN. Right. I would just say that the committee, I mean this issue has these 2 sides, which is you want to be able to take terms of a contract to another pharmacy if you can——

Mrs. ELLMERS. Um-hum.

Mr. HOLTZ-EAKIN [continuing]. Wouldn't that be great, but can you cut a deal with as good of terms and——

Mrs. ELLMERS. Um-hum.

Mr. HOLTZ-EAKIN [continuing]. How does that balance out. There has been a lot of work done by the Federal Trade Commission whose sole mandate is to identify pro-consumer aspects of the competition, and they have found these preferred networks are very effective in helping beneficiaries and consumers. And I think the committee should look at that, and I think CMS should look at that one.

Mrs. ELLMERS. Um-hum. Um-hum. Thank you. Mr. Schmid, you know, in my years as a nurse, certainly, one of those groups of patients that I have had the honor of taking care of and come to know, and their families I have come to know, are our HIV and AIDS patients. So first of all, I just want to thank you for all of the work that the institution is doing, because you are a vital, vital voice in how much treatment has advanced for our AIDS patients.

And I just want to ask your opinion. With the provisions that are being put forward in this proposed rule, is this not going to have

a negative effect on our Medicare Part D patients who especially are receiving AIDS treatment?

Mr. SCHMID. Yes, well, right now they are not proposing to eliminate access to antiretrovirals, but as I mentioned in our testimony, we are just concerned we could be next. And the criteria that they came up with, it was very arbitrary, the 7 days initiate——

Mrs. ELLMERS. Um-hum.

Mr. SCHMID [continuing]. Medication that will result in hospitalization or disability for——

Mrs. ELLMERS. Um-hum.

Mr. SCHMID [continuing]. A typical patient. They are not looking at a Medicare patient. Yes, we are very concerned and—for the future and the harm that it could have to patients.

Mrs. ELLMERS. Um-hum.

Mr. SCHMID. But most immediately, it would have harm to those who need immunosuppressants and antidepressants, and in the future, antipsychotics. And as I said in my testimony, a lot of people with HIV also have mental health issues.

Mrs. ELLMERS. Yes.

Mr. SCHMID. And so, you know, around 50 percent. So we are very concerned about access for medications for them. And then our organizations also advocates for people with Hepatitis——

Mrs. ELLMERS. Um-hum.

Mr. SCHMID [continuing]. Who undergo——

Mrs. ELLMERS. Um-hum.

Mr. SCHMID [continuing]. Liver transplants, and they need immunosuppressants as well.

Mrs. ELLMERS. Immunosuppressants, absolutely. Thank you.

And, Mr. Baker, I just have a quick question for you. The proposed rule change, CMS actually pointed out that, in this discussion that has already gone forward, and hopefully we are going to be able to have enough time for a future discussion, although I think that that time is falling short. The safeguards that are in place, do you feel that these patients are being safeguarded enough? And, as we have discussed, the idea that we are actually saving money—some of CMS' own findings are showing that this is not the case. What do you say to that? And I will just make one point that CMS put forward April 2013. It basically pointed out, it said negotiated prices—pricing for the top 25 brands and 25 generics in Part D Program at a preferred retail pharmacy is lower than a nonpreferred network pharmacy.

How do you justify the position that we are actually going to be saving money when we are already doing that, but by making this proposed rule change, that we will end up saving more money?

Mr. BAKER. I think there are projections and—on both sides of the ledger, as it were, from various actuaries. I mean, we certainly think that, given the track record that Part D has had thus far, and the stewardship that CMS has been engaged in, that the proposal will lead to lower costs not only for consumers but also for the program itself. And so I think—and that is because of the—any willing provider that has been in the pharmacy network overall, we are thinking that same will happen in the preferred network.

Mrs. ELLMERS. Um-hum. So we are projecting that, but we aren't seeing those results though.

Mr. BAKER. Well, there is a lot of——

Mrs. ELLMERS. Thank you. And I apologize, Mr. Chairman. I have gone over my time.

Mr. PITTS. Chair thanks the gentlelady. And now recognizes the gentleman from Maryland, Mr. Sarbanes, 5 minutes for questions.

Mr. SARBANES. Thank you, Mr. Chairman. Thank the panel.

I wanted to talk first about the consolidation idea which I think is a good one. I know the premise of Dr. Holtz-Eakin's perspective is that if you reduce the number of options that are available, that undermines competition, that ends up being a problem in terms of better prices for the program, and a better set of offerings for the beneficiary and so forth, but in order for there to be a competitive environment, the people making the choices have to feel that they can choose 1 over the other. And my understanding, Mr. Baker, is that the evidence suggests that when seniors have that opportunity to make a change, they are so typically overwhelmed by the number of options that are available, that they just choose to stick with the plan they have. And the competition that you want to encourage among the providers, among the plans, is both with respect to any new beneficiaries that are coming in, but also more so with the existing pool because that is the bigger part of the opportunity.

So if, as a practical matter, seniors are coming and saying, well, I am in this plan, and yes, I can go choose a different one, but I am not going to sit here and go through all of these different offerings, then the market is not really working. I mean the assumptions that your perspective are based on don't hold. And so if you reduce and consolidate this dizzying array of options that are available, you may actually get more people choosing something different, which will send a signal to the plans that are offering these opportunities that they have to compete more robustly.

Now, moving to the issue of the preferred pharmacy providers and so forth. I think it is outrageous that there—you have independent community pharmacists that are essentially being locked out of the opportunity to participate in a preferred pharmacy network, even when they are willing to accept the same terms. In a way that is happening, and I had the benefit of pharmacists in my district in Halethorpe, which I represent, a fellow named George Garmer who actually came and sat with me and kind of took me through his experience, and it may even be that the Maryland woman you are talking about was one of his customers, because it sounds very much the same, but she really couldn't stick with his pharmacy because the way the copayments were being differentiated between those who were able to be in the preferred pharmacy network and his situation meant that she was going to pay another $300 a year if she wanted to continue to go to the pharmacy that she had been going to for 40 years, and where she had a relationship.

So getting to this issue of the market and how it works, there is the theory and there is the practice. And I notice that in your testimony, you made the statement, Mr. Baker, that with this kind of pharmacy provider network manipulation, plans distort market behavior by lowering beneficiary cost sharing where the full cost of the drug is the same or higher than it would be at nonpreferred pharmacy. And this is important. Instead of harnessing the power

of consumer choice to lower costs overall by aligning lower cost sharing with lower total costs, the plans divide the interests of individual beneficiaries on the one hand, and the Medicare Program on the other, in order to increase the profits of related entity mail-order pharmacies. That is not the way it should work, and I just want to give you another opportunity because I feel pretty passionately about this, just based on this particular constituent who came and brought it to my attention, if you could speak again as to why this is a distortion of the market that we are supposedly trying to encourage here.

Mr. BAKER. Right. I think the distortion is exactly as you said, and that is that these lower cost sharing for beneficiaries into these preferred networks is not matched by, in many instances, in some instances by actual lower prices for the program. And so you are, you know, steering, if you will, beneficiaries to higher cost pharmacies that are either chain pharmacies or pharmacies that are wholly or partially owned by the plans themselves. And plans are reaping and pharmacies are reaping profits from that.

We really think that the interests of the program and beneficiaries should be aligned, not only for lower prices, but also because beneficiaries care about the sustainability of the Medicare Program and of this benefit, and to the extent that there can be that win-win, and also at the same time allowing community pharmacists into the equation to provide the services that they have been providing, you have more access at lower prices.

Mr. SARBANES. My time is up, but I will just note that if you have more transparency, it will promote better alignment, I think——

Mr. BAKER. Yes.

Mr. SARBANES [continuing]. By definition. Thank you.

Mr. PITTS. Chair thanks the gentleman. Now recognizes the gentleman from Virginia, Mr. Griffith, 5 minutes for questions.

Mr. GRIFFITH. Thank you, Mr. Chairman. And, Mr. Chairman, I appreciate you having this hearing, and this is one of those hearings where it has put me into a dilemma of sorts because I have great concerns that CMS doesn't have the authority to do a lot of things that they are doing in this rule-making process, and I noted with interest Dr. Gingrey earlier brought up the report from the CRS, and one of the things that he didn't mention is that what they are attempting to do is to take the legislative language and shift an "and" to an "or," and that causes me as an attorney who believes that the agencies ought to do what the law says, and if there is a problem come back to us, that they ought not be changing the law unilaterally, and that they ought to be exercising the constitutional prerogative of bringing their suggestions and their recommendations to the United States Congress.

So on that side, I agree with many of the comments of my colleagues on this side of the aisle. On the other side, I represent a fairly rural district, and while it may be lowering the price somewhat to have the preferred network, if the preferred network, the chain pharmacy, is located 20 miles away and around the other side of the mountain, I have people who aren't being adequately served by this program.

And so, gentlemen, I ask you, how do we solve that problem? How do we solve the problem where we may be getting the price down, but we are making it very, very difficult for my constituents to get to see the pharmacist who is prescribing their drug, and who—and, you know, in these rural areas, particularly a rural, mountainous area where they may not have but one pharmacy, and if that pharmacy is not in that particular town, part of this preferred network, and they have to go to the next town over, it may be a good distance. And particularly when most of these folks may not really like getting out driving, particularly, as we have had this winter, a fair amount of snow. How do you solve that problem? And I don't mind putting a bill in if that is what you think we need to do, but I do think that, Dr. Holtz-Eakin, it may impact the pricing somewhat, but there is a big difference between walking down the block in New York City and getting from Haysi to Clintwood.

Mr. HOLTZ-EAKIN. I agree with that completely, and I am not familiar with your district so I won't pretend too much knowledge, but we won't have to solve all problems with the same provisions. And the overall goal of this should be to get prescription drug coverage at as low cost possible for beneficiaries. I mean that is a key feature of the design.

Now, which vender delivers that, I don't think we should have a stake in. Perhaps mail-order is better for some of your folks as opposed to traveling at all. Have it delivered to their home. We need to make sure that we have a system that allows the negotiations to be as intense as possible with the manufacturers to get prices down, and then use a variety of delivery mechanisms to get them to seniors. And I think that should be the overall objective. No question.

We should trust the seniors to figure it out.

Mr. GRIFFITH. Well, of course the problem, in all fairness, with mail-order is if you have questions or if you have had a little rash that might have been caused by that, your pharmacist is in a far better position than your UPS or mail deliverer to——

Mr. HOLTZ-EAKIN. OK.

Mr. GRIFFITH [continuing]. Explain to you that, well, that is actually one of the side effects buried way down in the notes I have here.

Mr. HOLTZ-EAKIN. I would concur, and I——

Mr. GRIFFITH. And so that is another problem that I have.

Mr. HOLTZ-EAKIN [continuing]. Almost never have a—discussion. But I guess the second thing I would say is not all competition is on prices. We do want low prices, but there are many services associated, you know, advice about prescriptions, people are worried about seniors being in the right plan, well, we trust people to make choices right up to the age of 64 on the exchanges, and 65 suddenly they are incapable? I think they can probably figure it out, but if they can't, they can talk to their pharmacist, am I in the right plan, this what I typically have. You know, there are some other aspects——

Mr. GRIFFITH. I am running out of time.

Mr. HOLTZ-EAKIN [continuing]. That could be——

Mr. GRIFFITH. I do want to give Mr. Baker an opportunity to resolve the dilemma, and you may want to touch on how the CMS

has the legal authority to go forward with what they are doing, even though I agree with you on the any willing provider portions.

Mr. BAKER. I think that 2 things. One is that, certainly, there is a balancing here, and the example that we have in our testimony was a $300 difference. So I mean I don't think the service component allows that person to afford the $300 at the local community pharmacy. So I think, once again, the any willing provider is, I think, a moderate solution. I mean, I think for 2 reasons I am the wrong person to ask about the interference piece, one, because I am not—I am a lawyer but I am not, I don't think, qualified to do this constitutional interpretation, and——

Mr. GRIFFITH. But you do agree there is a difference between and and or.

Mr. BAKER. I would agree——

Mr. GRIFFITH. As a lawyer, you know there is.

Mr. BAKER [continuing]. With that.

Mr. GRIFFITH. Yes.

Mr. BAKER. I will agree with that.

Mr. GRIFFITH. Yes. Absolutely. And so that is my concern. And I hate to cut you off because I am running out of time.

Mr. BAKER. Sure.

Mr. GRIFFITH. I have other concerns about both the rule and the fact that maybe it is time for us to take a look at some of the things that may be working to a disadvantage. I have another letter here from one of my pharmacists who is in a specialized area, and they can't even figure out what they are going to get paid until after they have already provided the drug because of the way the system is set up, but that—I will have to deal with that another time because my time is out.

I do appreciate it. I have been—this hearing—totally, Mr. Chairman, I have been educated even more on this subject matter, and do appreciate it, and that is why we have these discussions and it is good to have.

Thank you, sir, and I yield back.

Mr. PITTS. Chair thanks the gentleman, and we will provide questions to you, if you will please respond in writing promptly.

I remind members that they have 10 business days to submit questions for the record. And I ask witnesses to respond promptly. And members should submit their questions by the close of business on Wednesday, March 12.

Dr. Burgess, you have a unanimous consent request?

Mr. BURGESS. Yes, Mr. Chairman. I have an opinion piece from June of 2012 that almost prophetically foretold the problems that would be visited upon the Part D Program by the Affordable Care Act, and I would like to submit that for the record. It was a very insightful piece that was written.

Mr. PITTS. Without objection, so ordered.

[The information follows:]

BURGESS: Medicare-less

Patients will have fewer options under Obamacare

By Rep. Michael C. Burgess Wednesday, June 6, 2012

When it comes to medical care, patients - not bureaucrats - know best what works best for them. While that sounds obvious to most Americans, in Washington, unfortunately, it's uncommon wisdom.

Medicare Advantage was first created as an alternative option to the Medicare fee-for-service program allowing patients the choice to enroll in a private-sector health plan. It now amounts to as much as 28 percent of the Medicare market, roughly $150billion per year. These plans, which usually have out-of-pocket maximums of $6,700 per year to protect beneficiaries from catastrophic medical expenses, serve as a lifeline for millions of American seniors.

Unfortunately, by 2014, when Obamacare goes into effect, the program will be unrecognizable. The new rules will give health insurers a financial incentive to chase arbitrary targets from years before, instead of simply providing Americans with high-quality, affordable care. Because it is dated and ignores the beneficiaries, the information the federal government will provide regarding Medicare Advantage programs will be fundamentally misleading.

Since 2008, Medicare Advantage plans have been graded from one to five stars, with plans rated four stars or greater being eligible for bonus payments from the government. Competition for enrollees plus bonuses for stars are incentives for better performance. It sounds good, right? That's not how it's been implemented.

They crunched numbers for cancer and cholesterol screenings for 2010, and flu vaccinations for February through June 2011 - excluding peak flu season in the fall - and applied a complex combination of 34 other measures over six different time periods, all ending three months before the insurance companies had any idea what yardsticks the government was using to measure them.

About the only thing they left out is where to use the divining rod.

If that all sounds more like witchcraft than modern medicine, it's because it is. In fact, by the time the government issues its criteria for grading the stars plans, insurers would be already past the date at which they can change their plans for the following year.

In 2013, the year before Obamacare goes into effect, Medicare Advantage beneficiaries will find themselves in stars plans based on statistics from 2010 - numbers which were already out of date before the law even passed.

The saddest irony is that under Obamacare, less than half of America's poor will have access to a four-star plan to begin with. And wasn't providing them with good health care the whole point of the law in the first place? Isn't that why Congress called it the Affordable Care Act?

Highly rated plans skew heavily in favor of whiter and wealthier populations. In 2012, Medicare Advantage plans rated four stars or higher are available for 50.9 percent of eligible beneficiaries, in 32.8 percent of all counties. But for counties with poverty rates of 25 percent or higher - the poorest 9.3 percent of counties - only 13.4 percent of beneficiaries have access to four-star plans.

In other words, under Obamacare, the poor, minorities and seniors on tight budgets will face even greater impediments to purchasing good health care plans. Because the stars system will encourage

insurance companies to provide only plans that earn four or five stars, and eventually scrap the rest, those people may lose their Medicare Advantage option.

Government works best when it creates fair and sensible rules, and allows companies to compete [illegible] to deliver quality goods. The rules should be predictable, and they should encourage insurance companies to improve care results in the eyes of the patients themselves, not based on nonsensical Washington yardsticks.

The Medicare Advantage market so many seniors have come to rely on came closer to that before Obamacare became law, but it's still possible to make it more competitive today.

The purpose of the stars program is respectable: Encourage plans to provide higher quality care for Medicare Advantage patients.

If Medicare structured its incentive program in a manner that allowed Americans to choose the plans that best met their needs, it could reward companies for providing better health care to more people at a lower cost - something we should all celebrate.

Ultimately, that's not all that hard: Put choices in the hands of the patients, not the politicians.

Rep. Michael C. Burgess, a physician and Texas Republican, is chairman of the Congressional Health Care Caucus.

Mr. PITTS. This has been a very informative hearing, very important issue. Thank you very much for your——

VOICE. Thank you.

Mr. PITTS [continuing]. Patience.

Without objection, the subcommittee is adjourned.

[Whereupon, at 1:24 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

Opening Statement of Chairman Fred Upton
Health Subcommittee Hearing on "Messing with Success: How CMS' Attack on the Part D Program Will Increase Costs and Reduce Choices for Seniors"
February 26, 2014

Today we examine the administration's proposed Medicare Part D rule, which – by undermining the foundation of this successful program – will raise costs for our nation's seniors and limit their choices.

As we have discussed many times, the financial sustainability of Medicare is under serious threat, putting the quality of care for future seniors in jeopardy. The Medicare Part A trust fund is forecasted to run out in 2026, and the cost of Medicare Part B is projected to double over the next decade. Medicare must be reformed for us to keep our promise to today's seniors and for generations to come.

With Medicare already facing such daunting challenges, it was deeply disturbing to learn that CMS is pursuing any policy that would undermine the Part D Prescription Drug Plan – the part of Medicare whose design has proven to be the most effective model at keeping costs under control and providing voluntary coverage options that seniors like.

The cost of Medicare Part D is less than half the level projected a decade ago. It has saved seniors hundreds of dollars in premiums every year and the federal government tens of billions of taxpayer dollars. It gives seniors choices and control over how they receive their drugs. This competitive structure demands innovation from providers to improve services and drive down costs and allows the flexibility for providers to innovate and improve services.

The linchpin of the Part D program's success is the principle of non-interference with negotiations between plans, pharmacies, and drug companies. This allows drug plans to drive a hard bargain with providers, and the ability to deliver savings for enrollees. It insulates the program from political micromanagement, ensuring that seniors only need to pay more if they genuinely value additional services that impose extra costs.

The proposed rule, issued on January 6, 2014, appears to be a direct assault on the competitive structure of the program. It inhibits the ability of plans to obtain discounts for beneficiaries, limits the range of market segments in which they may compete, and usurps the responsibility of states to license those able to prescribe. This 700-page proposal makes numerous changes, and we intend to look carefully at the many issues that it raises and how they would affect seniors.

This sudden proposed disruption to a program that has been functioning so well raises questions about whether CMS can be trusted to exercise the restraint needed to properly oversee modern market-oriented health care programs. Medicare Part D should be looked at as a model. We should build upon the successes of Part D as a benefit that meets the needs of enrollees and keeps costs under control, rather than trying to undercut what it has been able to achieve.

I hope that the witnesses today will bear in mind the long-term challenges that Medicare faces and the importance of innovative modern benefit structures to the future solvency of the program.

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS

Congress of the United States
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April 1, 2014

Mr. Jonathan Blum
Principal Deputy Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Mr. Blum:

Thank you for appearing before the Subcommittee on Health on Wednesday, February 26, 2014, to testify at the hearing entitled "Messing with Success: How CMS' Attack on the Part D Program Will Increase Costs and Reduce Choice for Seniors."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

Also attached are Member requests made during the hearing. The format of your responses to these requests should follow the same format as your responses to the additional questions for the record.

To facilitate the printing of the hearing record, please respond to these questions and requests with a transmittal letter by the close of business on Tuesday, April 15, 2014. Your responses should be mailed to Sydne Harwick, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to **Sydne.Harwick@mail.house.gov**.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Joseph R. Pitts
Chairman
Subcommittee on Health

cc: The Honorable Frank Pallone, Jr., Ranking Member, Subcommittee on Health

Attachments

Jonathan Blum
"2015 Changes to the Medicare Advantage and the
Medicare Prescription Drug Benefit Programs"
U.S. House Committee on Energy & Commerce, Subcommittee on Health
February 26, 2014

Attachment 1—Additional Questions for the Record

The Honorable Michael C. Burgess

1. **In the December 6 draft guidance on Part D and hospice, I also noticed that CMS repeatedly cited the perspective that a beneficiary's need for medications unrelated to their terminal condition will be "extremely rare." As a physician, I can tell you that this perspective does not align with the clinical reality of patients with multiple chronic conditions who are approaching the end of life. Much depends on the timing of the hospice admission and varies on a patient by patient basis. The final months and weeks of life are extremely complex, if anything. Please tell me how CMS is going to ensure that the physician's clinical judgment and the sacred relationship between a physician and patient is going to be preserved once CMS moves forward with a policy rooted in such a problematic assumption.**

Answer: CMS issued the December 6, 2013 memorandum in order to clarify the criteria for determining payment responsibility under the Part A hospice benefit and Part D for drugs for hospice beneficiaries. We issued this guidance for industry review and comment. The comment period ended on January 6, 2014. As we finalize the December 6 memorandum, we will take into consideration all comments and the various clinical scenarios in order to minimize any barriers to access to prescription drugs at the end of life.

2. **Also related to proposed changes to Part D in the December 6 draft guidance from CMS on the intersection of Part D and hospice, the OIG looked at the programs and found some duplication in billing for drugs related to terminal condition. And while OIG recommended education to the stakeholder community, my read of the draft guidance and related directives from CMS is that there is currently a recoupment effort underway that assumes all analgesics prescribed to a patient on hospice must be related to a patient's terminal illness. Is this correct? CMS is making a blanket clinical determination that if a patient is dying—any pain they are having couldn't possibly pre-date the terminal condition? So, if a septuagenarian who is dying of a condition that rarely presents with pain, such as congestive heart failure (CHF), has also been suffering with a 30 year old back trauma and related surgeries, it is CMS' opinion that the analgesics used to relieve that back pain are related to the terminal diagnosis of CHF?**

Answer: In 2013, CMS instructed Part D sponsors to delete questionable Prescription Drug Event records identified as duplicate payments for analgesic prescriptions filled within the dates of the beneficiary's Medicare Hospice election during the 2011 and 2012 plan years. This

recoupment effort has been completed. There is no recoupment effort currently underway for duplicate Part D payments for beneficiaries enrolled in hospice. For prescription drugs to be covered under Part D when the enrollee has elected hospice, the drug must be for treatment of a condition that is completely unrelated to the terminal condition(s) or related conditions; in other words, the drug is unrelated to the terminal prognosis of the individual. We expect drugs covered under Part D for hospice beneficiaries will be extremely rare. Therefore, the sponsor should place beneficiary-level Prior Authorization requirements on all drugs for hospice beneficiaries to determine whether the drugs are coverable under Part D. As a general rule, hospice providers are expected to cover virtually *all* drugs for hospice beneficiaries during the hospice election. The hospice provider will be responsible for coordinating with Part D plan sponsors for those drugs they believe are completely unrelated to the terminal illness and/or related conditions to determine payment responsibility. Any drug, including analgesics, may be unrelated to the terminal illness and/or related conditions and, therefore, coverable under Part D. As a result, coverage determinations must be made on a case-by-case basis for each drug.

3. **CMS proposes to require Part D sponsors to offer and publicly post standard terms and conditions for network participation that list all combinations of cost-sharing and negotiated prices, similar to the way fee schedules work in traditional Medicare. CMS has suggested through the proposed rule that opening up the preferred pharmacy arrangements to all pharmacies would lower overall costs by allowing more pharmacies to participate in the preferred cost-sharing reimbursement rate.**

   However, we understand that basic contracting strategy in the private sector requires that a Part D plan provide incentives to increase the volume of prescriptions and general customer foot traffic expected before a pharmacy agrees to lower costs. This is the experience of pharmacies and plans not only in Medicare Part D, but also in the private insurance marketplace. CMS seems to believe that this is not true. On what economic principles or negotiating experience is CMS basing this belief?

Answer: We have heard a number of comments in response to this proposal. We appreciate your concerns and look forward to reviewing all comments. We will take all views into account when deciding whether and how to finalize this proposal.

4. **CMS has significantly reduced the reimbursement level for some commonly performed procedures, specifically two epidural injections in the neck and lower back (CPT 62310 and 62311). The rule states that reimbursement will be $42 for a physician for 31 minutes of work, 20 minutes of preoperative and 11 minutes intraoperative time, and nothing for postoperative follow-up. Many physicians are unable to function and provide these services. It will soon affect the patients and these services will be moved into different locations or different procedures will be provided with a much higher expense, or they may even be stopped altogether.**

   Based on a request from CMS in 2012, the American Medical Association (AMA) Relative Value Scale Update Committee (RUC) surveyed these codes. The AMA stated that the data was inaccurate and recommended NOT to reduce reimbursement for the 2 codes. CMS did not accept the RUC recommendations with the only stated reason

being the reduction from the current work RVU was not comparable to the reduction in time being recommended by the AMA RUC.

a. Does CMS have any plans to review the new rates it has proposed?

Answer: These changes in the payment rates for epidural injections in the office setting were made as part of our efforts to improve payment accuracy by reviewing potentially misvalued codes. CMS has adopted a process to consider and, as appropriate, revise values for codes that are considered as part of the potentially misvalued codes initiative. Under that process, we establish values for misvalued codes on an interim basis in the final rule subject to public comment. We consider public comments on the interim final values received in response to the final rule, and respond to those comments in the final rule for the following year. In accordance with this process, we have established interim final values for these epidural injection services in the Calendar Year (CY) 2014 Physician Fee Schedule (PFS) Final Rule with comment period. The comment period on these values closed on January 27, 2014. We will consider public comments in establishing values for the codes in the CY 2015 PFS Final Rule. We intend to address public comments on these and other interim value codes adopted in the CY 2014 PFS Final Rule with comment period in the CY 2015 PFS rulemaking process.

b. In light of AMA RUC's recommendations of these two codes, why did CMS choose to move forward against RUC recommendation?

Answer: In our CY 2012 PFS Final Rule with comment period, we identified epidural injections as a high expenditure service that had not been recently reviewed. We used the survey times submitted by the American Medical Association (AMA) Relative Value Scale Update Committee (RUC), which were based on surveys of a sample of physicians who furnish the service, and recommended practice expense inputs to establish interim final values for the epidural injection code family in the CY 2014 PFS Final Rule with comment period. The interim final revised work and practice expense values established in the CY 2014 PFS Final Rule with comment period reflect the reductions in time required to furnish the service as a result of the surveys submitted with the AMA-RUC-recommended values and the expectation that reductions in the time required to furnish the service reasonably results in reductions to the work and practice expense values associated with the service.

c. Has CMS considered the tremendous risk associated with these procedures and the skill required to perform these procedures and the extremely high risk of malpractice suits with poor outcomes?

Answer: CMS understands that this change in the physician fee schedule has resulted in CY 2014 payment reductions for the epidural injection services when furnished in the physician office. However, we believe that it is critical to continue to refine Medicare payments to more accurately pay for physicians' services. We assigned values based upon our estimates of the resources used in furnishing the services in the physician office and our usual methodology. We note that the payment rates in 2014 for epidural injections in the physician office setting are interim final values established by CMS. There was a 60-day comment period on these values which closed on January 27, 2014. We will consider and address the public comments we

received, including any comments on the risks and skills associated with these services, in establishing the values for the codes in the PFS rulemaking for CY 2015.

5. **Immunosuppressive therapies are not only highly specialized, but also have widely varied patient tolerance and response. In fact, I know that the toxicity associated with one type of drug is more significant for some patients than for others. And the consequences of formulary changes for these particularly fragile patients can often mean four results: severe pain, rejection of the organ, a return to dialysis, or even death.**

    a. **Was there a major medical breakthrough or change in the science on immunosuppressive drug treatments since 2005?**

    b. **So, why *now* does CMS find it advisable, or in any way acceptable, to allow Part D plans to limit the availability of these medications to specific drugs at the discretion of the insurers?**

Answer: In the CY 2015 Parts C and D Notice of Proposed Rulemaking, CMS set out to revise the regulations governing the Parts C and D programs as part of our annual rulemaking cycle. We periodically revise the regulations governing the Parts C and D Programs to implement statutory directives and to incorporate knowledge obtained through experience with each program. This proposed rule included provisions meant to reduce program costs and improve the quality of care for Part C and D enrollees.

We have heard a number of comments in response to this proposal. We appreciate your concerns and look forward to reviewing all comments. We will take all views into account when deciding whether and how to finalize this proposal.

<u>The Honorable Jim Matheson</u>

1. **The Committee heard a great deal about how important it is for vulnerable patients to have access to needed drugs, and how flawed Medicare policies can inhibit that access. When it comes to medical devices, limited or absent Medicare coverage policies and inadequate payment for medical devices can result in physicians being unable to offer certain new technologies to their patients without navigating a complex and often burdensome administrative process. This is true even when the patient is anxious to obtain the medical device on a self-pay basis. I have worked with Congressman Erik Paulsen to develop legislation, H.R. 3681, the Accelerating Innovation in Medicine Act, that would provide physicians and patients with the opportunity to cut through this red tape in circumstances where the manufacturer of a product has elected to make the device available on a self-pay basis while they undertake the clinical studies in order to obtain Medicare coverage and payment for their medical device. Are you familiar with this proposal, and do you feel it would expand the ability for doctors to offer new technologies to their patients?**

Answer: We are not aware of any provision of current law or policy that would prohibit Medicare beneficiaries from voluntarily purchasing a non-covered medical device on a self-pay basis. We have not fully examined H.R. 3681, but we would be happy to provide technical assistance, upon request, on any legislative proposals addressing this issue.

The Honorable Tim Murphy

1. **Were any other stakeholders, agencies, professionals, or others consulted when formulating this proposed rule?**

Answer: Yes, CMS consulted with beneficiaries, pharmacies, drug manufacturers, insurers, and other stakeholders in formulating this proposed rule. As the notice and comment period is still open, CMS has heard from only a segment of stakeholders. We will carefully consider the comments from all stakeholders when finalizing this rule.

2. **Who were the Protected Classes Review Panel members and why were they chosen to serve on the panel?**

Answer: Members of the Protected Classes Review Panel included CMS pharmacists and the Chief Medical Officer for the Center for Medicare. They were chosen for expertise that enabled them to identify which drug categories or classes met the proposed criteria to qualify as a protected class.

3. **Who was the contractor and how did the Review Panel use the contractor's research/information? What other steps and process did the panel undergo in conducting this analysis? Did it just rely solely on the information from the contractor?**

Answer: The panel was supported by Fu Associates, Ltd. and by Strategic Health Solutions (SHS). These contractors performed background research and provided specific information on Part D utilization and analyses of widely-accepted treatment guidelines for each drug category or class, when available. Fu Associates, Ltd. analyzed CY 2012 prescription drug event data to provide the following data elements: (1) the number of beneficiaries utilizing a drug within each American Hospital Formulary Service (AHFS)-6 class; (2) the number of beneficiaries utilizing more than one drug within an AHFS-6 class at the same time; and (3) the percentage of beneficiaries that utilized more than one drug at the same time. Strategic Health Solutions analyzed widely accepted treatment guidelines for the disease states treated by the AHFS-6 classes from which beneficiaries most commonly took multiple drugs. For each guideline, SHS determined whether the guideline supported concurrent use of multiple drugs within the class. If multiple drugs were supported, SHS then determined whether failure to obtain access to a drug within the class would result in major or life threatening clinical consequences.

The panel reviewed all Part D drugs that were included on the CY 2013 CMS formulary reference file and that had utilization in CY 2012, using the AHFS-6 classification system. The panel chose the AHFS-6 classification system as a framework because it allows for the grouping of drugs based on similar pharmacologic, therapeutic, and/or chemical characteristics; and,

therefore providing CMS with a tool to logically, and in stepwise fashion, apply the criteria to all Part D drugs.

As the panel reviewed therapeutic classes, the criteria were applied in order. Generally, with the exception of a few classes, if the panel determined that a class did not meet the first criterion, the determination of whether the class met the other criteria was unnecessary. Only if the panel concluded that a therapeutic class met all defined criteria, then the class was deemed as a protected class.

During the panel's review, additional consideration was given to CMS' current formulary review checks (*e.g.*, treatment guidelines review) which are intended to ensure beneficiary access to medically-necessary Part D drugs. The panel considered whether a more specific CMS formulary requirement than requiring all drugs in a class was already implemented or could be implemented to ensure appropriate access to classes of drugs.

4. **How specifically will the proposed removal of the protected class status for anti-depressants, immunosuppressants, and anti-psychotics achieve cost-savings for the agency?**

Answer: One goal of the proposed removal of the protected class status for anti-depressants, immunosuppressants, and anti-psychotics, is to introduce competition into the market for drugs in these currently protected classes. Because the current protected classes of drugs have guaranteed Part D formulary placement, manufacturers have no incentive to negotiate on price, or obtain price concessions such as manufacturer drug rebates which drives up costs. By removing protected class status for certain classes of drugs, manufacturers would negotiate Part D formulary placement of these drugs, achieving cost-savings for taxpayers. However, CMS is aware that stakeholders have expressed concerns about this proposed policy's potential impact on access to drugs in the current protected classes. We will carefully consider all stakeholder comments when determining whether to finalize this proposal.

5. **CMS states that the Medicare appeals process will ensure that beneficiaries have adequate access to medications outside of the protected classes, including antidepressants, immunosuppressants, and antipsychotics. Yet, the CMS appeals process is time consuming and subject to significant delay. On January 3, 2014, the CMS Office of Medicare Hearings and Appeals (OMHA)—the office responsible for the third level of Part D reviews—announced a public meeting to discuss "a growing backlog in the processing of Medicare appeals." How is an office that already has a significant appeals backlog going to provide beneficiary protection?**

6. **In the proposed rule, CMS claims that cut-backs in access to medications for vulnerable classes of clinical concern will result in cost savings. It is well-established that money saved by restricting access to medicines in Part D will be overrun by additional costs to Parts A and B through increased non-drug medical spending, in addition to clinical and societal costs that result from not managing serious and chronic conditions effectively through medication. As one example of the strong data contrary to CMS' position, a November 2012 CBO report on prescription drug savings announced a change to its**

cost-estimating methodology to reflect evidence showing that increases in prescription drug use by Medicare beneficiaries lead to offsetting reductions in Medicare's spending for medical services. Looking at the Medicare program as a whole, therefore, and balancing beneficiary access with cost considerations, how and why does CMS think the proposed changes to the six protected classes policy make sense, particularly on the asserted basis of cost considerations?

Answer to #s 5 and 6: CMS does not believe the proposed change to the protected class policy would adversely impact beneficiary access to needed medications, but we are aware of stakeholders' concerns about access to needed drugs. Among the current 134 non-protected classes of drugs, we have not observed problems maintaining a broad availability of drugs, including brand-name drugs. If the proposal is finalized, beneficiaries will still be able to receive the medications they need, and we observe that more than 80 percent of drugs in a class are included on formularies on average. Additionally, under current law, if a beneficiary needs a non-formulary drug, CMS has a formulary exceptions process in place that helps ensure beneficiaries can get the drugs they need. It is important to understand that this exceptions process is part of the upfront coverage determination process managed by Part D plan sponsors, and that exception requests need not progress into the appeals process as long as the prescriber provides the case-specific justification as to why the beneficiary cannot use a formulary alternative.

The comment period for this proposed rule is still open, and CMS welcomes stakeholder input. We will carefully consider all stakeholder comments when determining whether to finalize this proposed rule.

The Honorable Gene Green

1. **Serious mental illness continues to pose a significant public health and safety issue in our country. Access to all treatments that have been proven safe and effective for people with mental illness is critical to addressing this challenge. CMS Administrator Marilyn Tavenner stated that "Medicare beneficiaries have access to FDA approved products" in response to a question asked during her Senate Finance Committee confirmation hearing last year. Respectfully, there are indeed FDA-approved treatment options that are not covered by Medicare, and therefore, not accessible to Medicare beneficiaries. How does CMS intend to correct this issue and make approved treatment options, such as medical devices that are approved for the treatment of severe, chronic treatment-resistant depression, available to Medicare beneficiaries (including beneficiaries who are disabled due to their illness)?**

Answer: We share your commitment to services for persons with serious mental illnesses including beneficiaries who qualify for Medicare by reason of disability. We are also committed to providing timely access to new technology that meets the statutory criteria for coverage under Medicare. The primary avenue for such coverage is through the National Coverage Determination (NCD) process, in which CMS undertakes a comprehensive review all available

clinical and scientific evidence. Any person may request that CMS initiate such a review along with submission of relevant evidence.

While in many cases, Medicare coverage may follow FDA approval of an item or device, the statutory obligations and standards are different for each agency. In particular, Medicare coverage is only authorized for items and services determined to be reasonable and necessary for the diagnosis or treatment of illness or injury in Medicare beneficiaries (or for screening and preventive services under limited circumstances). In some cases, an FDA-approved device may not meet this statutory standard. Any person may request reconsideration of an NCD with submission of appropriate new evidence.

The Honorable Phil Gingrey

1. **The Part D prescription drug program began in January 2006 and by all accounts, has worked well. However, as the Part D Program has evolved, access to pharmacies is now being limited through use of artificial price disparities. The concern is that many of our seniors are being forced to leave pharmacies they have frequented for years. Aside from aggravation, this dynamic has a more problematic impact on seniors in rural areas, who may not have anyone other than an independent pharmacy to fill their prescriptions. My understanding is that most local pharmacies are willing to participate in a manner that would have no additional costs to the Part D program. Does CMS agree with that position and if so, how did you come to that conclusion?**

Answer: We heard from many pharmacies, many of them small independent community pharmacies, that plans do not offer any willing pharmacy the opportunity to offer preferred cost-sharing. Instead, some pharmacies are being offered only the plan's standard terms and conditions, at the highest level of beneficiary cost-sharing. Our analysis of the 2012 claims shows that there is wide variation in discounting across sponsors. Consistent savings are not seen uniformly. In some cases, pharmacies extending high discounts are ones that have been excluded from limited networks offering preferred cost-sharing, while some pharmacies within the limited networks offer effectively no discounts compared to the rest of the network. Given the variation, we will carefully evaluate the comments we receive on this proposal, including any economic analyses, and would re-examine our position if warranted.

2. **In your view, are Part D preferred pharmacy networks decreasing or increasing patient access to pharmacy services?**

Answer: As the number of plans offering preferred cost-sharing has increased, various parties have drawn our attention toward concerns with these arrangements, particularly regarding beneficiaries' access to the advertised lower cost-sharing in these plans. In order to further analyze this issue, we have awarded a contract to study beneficiary access to preferred cost-sharing. This study will analyze beneficiaries' geographic access (*i.e.*, time and distance) to pharmacies offering preferred cost-sharing in plans' networks. . Based on the results of this study and comments received to date on the draft Call Letter and the proposed rule, we will evaluate

whether we should set standards for network adequacy for pharmacies offering preferred cost-sharing, similar to current standards for retail network adequacy.

3. **Pharmacy Benefits Managers are claiming credit for the fact that Part D programmatic costs are coming in far below government estimates. Is it CMS' position that the reduced costs are primarily attributable to the role played by PBMs? Or are there other factors that have contributed to the reduced cost estimates?**

Answer: Costs in the Part D program are lower than projected for several reasons, including an increase in generic prescribing, as well as the fact that there are fewer blockbuster medications in the market right now than both the CMS actuary and the CBO projected in 2003.

4. **With regard to many Part D Plan sponsors and pharmacy relationships, it appears that CMS has conducted a number of internal or blind studies concerning PBM operations. Some of those findings allege inconsistencies in important areas of the program, including PBMs misreporting or gaming contracts, shifting low income cost-sharing, etc. According to one study, CMS has observed these practices and found them to have limited market competition, created barriers to entry, and undermined program transparency. Please submit copies of such studies that have been conducted by CMS from 2006 forward.**

Answer: CMS has not conducted internal or blind studies on Pharmacy Benefit Manager operations in the timeframe referenced.

5. **When concluding that the protected classes policy increases costs to Medicare Part D, what analysis did CMS conduct to estimate the offsetting costs to Parts A and B that may result from increased hospitalizations, physician visits, and other interventions when beneficiaries' access to antidepressants or immunosuppressants to prevent rejection of transplanted organs is restricted?**

Answer: In our evaluation of the protected-classes proposal, we assumed there to be no change beneficiary access to clinically-necessary prescription drugs. Accordingly, we assumed that there would be no impact on the usage of Medicare Part A and Part B services.

6. **MedPAC's staff conducted beneficiary focus groups regarding Part D appeals, the findings of which were discussed at the September 2013 MedPAC meeting. MedPAC staff found that a majority of beneficiaries did not know they had appeal rights. MedPAC staff also found that most beneficiary counselors saw the Part D appeals process as a "last resort" and instead encouraged beneficiaries to switch plans (if low-income subsidy eligible), apply to manufacturers' assistance programs, or ask physicians for samples. Given these findings, how can CMS claim that seniors and disabled people suffering from depression are going to maneuver successfully through this process and win an appeal in 7 days? (All this while the patient is going without his or her prescribed antidepressant during this 7-day period.)**

Answer: Current Part D formularies maintain broad availability of the drugs seniors rely on, and we expect they would continue to do so under the proposed changes to the six protected classes.

We have heard that beneficiaries are unaware of their appeal rights. In our experience, beneficiaries typically are not aware of their appeal rights until there is a problem accessing a drug, so it makes sense it is not something all beneficiaries are familiar with in advance. That is why, since 2012, we have required sponsors, through their network pharmacies, to hand our beneficiaries printed instructions on how to use their right to a coverage determination whenever a prescription cannot be filled.

Further, it is important to understand that the exceptions process is part of the upfront coverage determination process managed by the sponsors, and that exception requests need not progress into the appeals process as long as the prescriber provides the case-specific justification as to why the beneficiary cannot use a formulary alternative.

The Honorable Bill Cassidy

1. **If we want to modernize Part D, one thing we should look at is an outdated restriction placed in the law on coverage of obesity therapies. We cover behavioral counseling and gastric bypass surgery, but this key middle ground of care is banned from the program. With next generation products now on the market to combat obesity and with others likely arriving soon, shouldn't we remove this restriction so doctors can prescribe covered obesity therapies to their patients who really need them?**

Answer: The statutory definition of a Part D drug under section 1860D-(2)(e) specifically excludes agents used for weight loss.

The Honorable H. Morgan Griffith

1. **How does CMS respond to the concerns raised by the FTC in their March 7, 2014, comments on the proposed rule's any willing pharmacy provision for preferred pharmacy networks?**

2. **In deciding to not move forward with the any willing pharmacy provisions, did CMS make the determination that they did not have the authority to implement these because of the non-interference clause?**

Answer to #s 1 and 2: CMS cannot address any one comment outside the rulemaking process. We will carefully consider all comments as we finalize the rule and follow standard procedures to respond to each comment in that forum.

3. **Does CMS need statutory authority to apply an any willing pharmacy provision within preferred pharmacy networks? If so, what authority is needed?**

Answer: We believe that an alternative reading of sections 1860D-4(b)(1)(A) and 1860D-4(b)(1)(B) to reduce barriers to pharmacy participation in preferred networks is permissible. However, we will carefully evaluate the comments we receive on this proposal, including any economic analyses, and would re-examine this position if warranted.

4. **Given the rural and mountainous district that I represent, geography plays a large role in my constituents' lack of access to a preferred network pharmacy. In Southwest Virginia, some seniors have reported travelling upwards of 20 miles to get to a preferred network pharmacy, which might take an hour or more when they have to travel over mountains, especially in adverse weather. For seniors, I feel this is quite a burden, especially when there may be a local pharmacy there in the community where they live. How would CMS recommend narrowly tailoring changes to preferred pharmacy networks to ensure my constituents and other seniors in rural areas of this country have the same access to low cost drugs through preferred pharmacy networks?**

Answer: CMS' any willing provider proposal would allow any pharmacy, including community pharmacies, to match the competitive prices offered by preferred pharmacy networks, resulting in more competition, better access to lower-priced drugs for seniors, and the ability for seniors to maintain trusted relationships with community providers.

The proposal would mean that local community pharmacies could participate in a preferred network if they were willing to offer the same prices as their big box store competitors, helping beneficiaries who do not have nearby access to a big box retailer.

The Honorable Gus Bilirakis

1. **In December, I sent a letter with my House colleagues about our concerns about CMS' recent guidance related to Medicare Part D hospice care payments. We are concerned that the directive issued on October 30, 2013, to Part D plan sponsors to recoup from hospice providers payments for all pain medication dating back to 2011 is a substantial change in policy and process that goes back to the beginning of the Medicare hospice benefit. Such a significant change should be carefully considered to ensure patient safety and continued access to appropriate care at the end of life. In our letter, we requested that CMS work collaboratively with the Part D and hospice communities and other interested stakeholders on this issue. Please describe what actions CMS plans to take, if any, to work with these stakeholders to ensure any policy change does not impact Medicare hospice patients.**

Answer: We agree that CMS should work collaboratively with Part D sponsors and hospice communities to achieve shared policy goals that are consistent with current Federal law. Accordingly, we issued the December 6 memorandum for industry review and comment. During the 35-day comment period, we held discussions with stakeholders to listen to their concerns and respond to their questions. We considered all the stakeholder comments received as we finalized the guidance for 2014 and as we undertake our Medicare Hospice rulemaking for 2015.

2. **In issuing its Part D directive related to hospice care payments, CMS has stated that the existence of unrelated conditions, and therefore, the need for unrelated medications, is "very rare." If this is the case, what is the need for the continued assignment of Part D services once a patient elects hospice care? Why are beneficiaries required to pay premiums to have this coverage if their opportunity to utilize the coverage is "very rare" according to CMS? Has CMS considered suspending the Part D premiums once a patient has elected to invoke the hospice benefit?**

Answer: Although we expect it is extremely rare, beneficiaries who have elected hospice may be prescribed a medication for a condition that is completely unrelated to the terminal illness or related conditions. In such instances, we expect that the hospice provider or prescriber will immediately provide, to the Part D sponsor, the written documentation necessary to satisfy the Prior Authorization.

3. **Has CMS considered the possible unintended consequences to its Part D guidance related to hospice care payments? There is a strong possibility that patients will experience access issues, such as rejections by the pharmacy for medications previously covered by Part D, and will interpret this as a barrier to care associated with the hospice benefit. We have already heard that a number of pharmacies have already been instructed to not bill prescription orders for hospice patients under Part D under any circumstance, secure an alternative source of funding for the medically necessary drugs or deny the prescription order. These access issues are likely to lead to revocation of the hospice benefit and the patient will return to their previous Medicare coverage. With this coverage, they will continue to gain access to all medications through the Part D benefit and will also continue to utilize other Part A covered services such as physician visits, laboratory services, imaging services, emergency room visits, and hospitalizations. It seems counterintuitive to create barriers for access to a proven cost-saving benefit such as the hospice benefit in order to create a relatively small savings generated through the restriction of Part D billing for hospice patients.**

Answer: CMS takes very seriously the care of Medicare beneficiaries who are hospice-eligible. We strongly believe CMS must take steps to ensure hospice providers and Part D plans understand our policies, have an opportunity to comment on proposed policies, and understand how to prevent improper payments for hospice beneficiaries' drug costs. It is for these reasons we issued the December 6 memorandum for industry review and comment. During the 35-day comment period, we held discussions with stakeholders to listen to their concerns and respond to their questions. We considered all the stakeholder comments received as we finalized the guidance for 2014 and as we undertake our Medicare Hospice rulemaking for 2015.

As we indicated in our recent guidance, for prescription drugs to be covered under Part D when the enrollee has elected hospice, the drug must be for treatment of a condition that is completely unrelated to the terminal condition(s) or related conditions; in other words, the drug is unrelated to the terminal prognosis of the individual. We expect that the use of drugs covered under Part D for hospice beneficiaries will be extremely rare. As a general rule, hospice providers are expected to cover virtually all drugs for hospice beneficiaries during the hospice election. The hospice provider will be responsible for coordinating with Part D plan sponsors for those drugs

they believe are completely unrelated to the terminal illness and/or related conditions to determine payment responsibility.

CMS is considering proposing through rulemaking certain provisions (*e.g.*, using an independent review entity to assist with the prior-authorization process as needed) that we were unable to finalize through sub-regulatory guidance. In the interim, we are taking steps to make the process easy for hospice providers and our beneficiaries so drug access can be maintained at all times. These efforts include: streamlining the Prior Authorization process in order to expedite the most timely access to drugs unrelated to a beneficiary's terminal illness or related conditions; providing the hospice with around-the- clock support through the sponsor's 24-hour pharmacy help desk; and working with the hospice and sponsor community to help facilitate communication.

Attachment 2—Member Requests for the Record

During the hearing, Members asked you to provide additional information for the record and you indicated that you would provide that information. For your convenience, descriptions of the requested information are provided below.

The Honorable Marsha Blackburn

1. **Please cite for me the statute that gives you the opportunity to go in and settle these disputes between the manufacturers and pharmacies.**

Answer: We proposed to interpret the prohibition in section 1860D–11(i)(1) on interference in negotiations to pertain to discussions between prescription drug manufacturers and pharmacies. Therefore, we proposed that CMS may not be a party to discussions between prescription drug manufacturers and pharmacies, and may not arbitrate the meaning of or compliance with the terms and conditions of agreements reached between these parties, except as necessary to enforce CMS requirements applicable to those agreements. We will carefully review the comments we receive on this proposal.

The Honorable Michael C. Burgess

1. **Please provide the Committee with the cost analysis that you did for this rule.**

2. **In the cost analysis, is there also going to be the delineation of the legal justifications for proposing the rule?**

Answer to #s 1 and 2: The cost analysis of the provisions of the proposed rule is provided in the Regulatory Impact Analysis. The legal justification is in the proposed rule's preamble.

3. **Why, after 10 years, did CMS feel it must now reinterpret the non-interference clause? What has changed that propelled you to make this distinction? Please provide the evidence you used to determine this.**

Answer: CMS proposed to interpret the non-interference provision in section 1860D-11 because we are periodically asked to weigh in on initial negotiations, disputes, and renegotiations. We do not believe this is appropriate, nor is it our role, given the statutory requirement not to "interfere" with negotiations between drug manufacturers and pharmacies and PDP sponsors. We will carefully review the comments we receive on this proposal.

4. **How do you anticipate how CMS' intervention in these negotiations would improve the program? What is your expectation of improvement?**

Answer: CMS anticipates that interpreting the non-interference provision will provide needed clarity to drug manufacturers, pharmacies, and PDP sponsors on when we will and will not become involved in their negotiations or disputes. We will carefully review the comments we receive on this proposal.

5. **Are you aware of the requirements to keep the proprietary contract terms confidential with the ACA? That is section 3301 of the PPACA. It seems to me that it would be contrary to the policy you are proposing in the Part D proposed rule.**

Answer: Section 3301 of the Affordable Care Act concerns the Part D Coverage Gap Discount Program and does not include any requirements to keep contract terms proprietary. As a result, we do not see any conflict between section 3301 and our proposed rule.

6. **Did you, Administrator Tavenner, or Secretary Sebelius receive any legal memoranda that provided you the ability to proceed forward with this rule and the proposed non-interference interpretation? Please provide the memoranda.**

Answer: No.

The Honorable Brett Guthrie

1. **Please provide the full complaint data that you referenced saying seniors do not like their Part D plans.**

Answer: We will work with your staff to provide information on Medicare complaints.

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS

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April 1, 2014

Dr. Douglas Holtz-Eakin
President
American Action Forum
555 13th Street, N.W., Suite 510 West
Washington, D.C. 20004

Dear Dr. Holtz-Eakin

Thank you for appearing before the Subcommittee on Health on Wednesday, February 26, 2014, to testify at the hearing entitled "Messing with Success: How CMS' Attack on the Part D Program Will Increase Costs and Reduce Choice for Seniors."

During the hearing, Members asked you to provide additional information for the record, and those requests are attached. The format of your responses to these requests should be as follows: (1) the name of the Member whose request you are addressing, (2) the complete text of the request you are addressing in bold, and (3) your answer to that request in plain text.

To facilitate the printing of the hearing record, please respond to these requests with a transmittal letter by the close of business on Tuesday, April 15, 2014. Your responses should be mailed to Sydne Harwick, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to **Sydne.Harwick@mail.house.gov**.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Joseph R. Pitts
Chairman
Subcommittee on Health

cc: The Honorable Frank Pallone, Jr., Ranking Member, Subcommittee on Health

Attachment

Question for the Record: E&C Health Subcommittee hearing – 02/26/2014

The Honorable Renee Ellmers

Question: How many plans will be eliminated as a result of the proposed Part D rule in North Carolina?

Douglas Holtz-Eakin, President American Action Forum

Answer: The county by county enrollment data from North Carolina show that very few plans with over 10 enrollees would be eliminated as a result of limiting issuers to two plans in each rating area. While AAF did not parse through every county, a sample of nine counties showed only four counties where a plan would be eliminated, and in each it was only one plan (leaving between 12-27 plans with over 10 enrollees intact).

From AAF's read of the data the majority of counties do not have significant enrollees on three plans offered by the same issuer; however, there may be plans at risk of elimination that are not apparent in the data because they have fewer than 10 enrollees in any given county and are thus not represented.

The provision in CMS's proposed rule that would prohibit preferred pharmacy networks would have a much bigger impact in North Carolina. In North Carolina, 572,525 Part D enrollees are using plans that utilize a preferred pharmacy network. Should CMS implement the policy as outlined in the proposed rule, that population, which represents 36.5 percent of the Medicare beneficiaries in the state, would be at risk of losing their plan, or having their plan altered to meet the new regulations, and their premiums increased.